

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4
5 INTAS PHARMACEUTICALS LTD.,

6 Petitioner,

7 V.

8 ATOSSA THERAPEUTICS, INC.,

9 Patent Owner.

10
11 Case PGR2025-00043
12 Patent No. 12,071,391
13 Case IPR2025-00799
14 Patent No. 11,261,151

15 Deposition of RON BIHOVSKY, Ph.D.

16 CONDUCTED VIRTUALLY

17 Tuesday, January 20, 2026

18 10:02 a.m.

19 Job No.: 614362

20 Pages: 1 - 306

21 Stenographically Reported By:

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

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

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5 *** ALL PARTIES ATTENDED REMOTELY. ***

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8 Pursuant to Notice, before Brooklyn E.
9 Schweitzer, Registered Professional Reporter,
10 Certified Realtime Reporter, California CSR No.
11 14612, and Notary Public in and for the
12 Commonwealth of Pennsylvania.

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A P P E A R A N C E S

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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.

1 Q What is Key Synthesis?

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

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

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

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

18 Q You understand that you submitted a
19 declaration in an IPR proceeding related to the
20 '151 patent, right?

21 A I do. Yes.

22 Q And you also submitted a declaration in a

1 PGR proceeding related to the '391 patent, right?

2 A That's correct.

3 Q Do you understand this deposition is --
4 withdrawn.

5 Do you understand this deposition pertains
6 to both of those proceedings today?

7 A I understand that.

8 MR. MILEA: If we could please bring up
9 the first exhibit, which will be IPR Exhibit 1033,
10 and I believe we can paste that in the chat.

11 (PGR Exhibit 1033 was marked for
12 identification and is attached to the transcript.)

13 BY MR. MILEA:

14 Q And, Doctor, I should ask: Do you have
15 any papers with you in the room today?

16 A Not much.

17 Q What do you have with you?

18 A I'll -- a piece of paper where I've
19 written down your name and your firm. I do have
20 copies of the various documents that were supplied
21 to me, but they're not in front of me.

22 Q Okay. If it's okay with you, what we'll

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

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

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

17 Is that all right?

18 A Sure, great.

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

21 Do you have that?

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

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

2 Q Okay. Perhaps we can scroll down.

3 A Okay. I agree -- I agree that I have
4 1033.

5 Q Do you recognize Exhibit 1033?

6 A Yes.

7 Q What is it?

8 A Expert declaration of me.

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

11 A Yes.

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

15 A So are you moving it or am I?

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

22 A Okay. So tell me how to do that.

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

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

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

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

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

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

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

19 THE WITNESS: No, I --

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

22 Now put your -- check your -- put your

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

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

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

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

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

19 THE WITNESS: Okay.

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

22 THE WITNESS: Right now, I'm seeing the

1 same thing you're seeing --

2 TECHNICIAN: Okay.

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

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

8 THE WITNESS: Okay. Double-click where?

9 TECHNICIAN: Just double-click on the
10 file.

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

13 TECHNICIAN: Yes.

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

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

20 MR. MILEA: That's okay.

21 (A recess was taken.)

22 BY MR. MILEA:

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

3 A Yes, I do.

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

6 A Yes, it is.

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

9 A Okay. I'm on 56.

10 Q Do you also see the Zoom screen?

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

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

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

17 Q Is that your signature on Page 56?

18 A Absolutely.

19 Q Okay. Let's now look at Exhibit 1034 in
20 the PGR, so that's your declaration related to the
21 '391 patent. If you could please pull that up,
22 Doctor.

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

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

5 A Okay.

6 Q Is your signature on that page?

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

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

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

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

22 A Okay.

1 Q Have you been an expert witness before in
2 a patent litigation or an IPR or PGR?

3 A Yes.

4 Q About how many times have you done that?

5 A I've been deposed approximately 15 times,
6 and I've testified at trial approximately seven
7 times.

8 Q In those cases, were you on -- withdrawn.

9 In those cases, were you retained by the
10 patent owner, the patent challenger, or a mix, if
11 you can remember?

12 A Generally, by the challenger, sometimes by
13 the owner.

14 Q What would be the split, generally?

15 A I would say 90 percent by the challenger.

16 Q Given that, I take it you've sat for
17 several depositions, if not more; is that right?

18 A Yeah. As I said, I've sat for
19 approximately 15 depositions.

20 Q 15. Okay. I'm sorry. I missed that.

21 So I think you know the rules, but I'll
22 just go through it so we're on the same page, if

1 that's okay.

2 A Okay.

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

6 A I understand.

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

9 A I will.

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

12 A Yes.

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

16 A Yes.

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

20 A Yes.

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

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

4 Is that okay?

5 A Yes.

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

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

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

13 A Absolutely not.

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

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

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

1 Q Okay. Thank you.

2 In chemistry, what is a polymorph?

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

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

18 Q How is it -- withdrawn.

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

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

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

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

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

18 A The conditions of the crystallization.

19 Q What do you mean by that?

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

22 Q Those conditions, do you mean external

1 factors?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 A Could you repeat the question, please?

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

14 A Yes.

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

19 A No.

20 Q What are you referring to?

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

22 Q Yes.

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

7 Q Sure.

8 A Would that be --

9 Q Maybe I can just short-cut this.

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

13 A Yes.

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

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

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

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

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

9 A Okay. Great.

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

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

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

22 A Yeah.

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

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

6 Tell me when you're there.

7 Q Yes, I'm there.

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

14 And then following that, the numbers in
15 parentheses are the ratio of the Z to E isomers.
16 And so just to elaborate on that, 15-27-1 is a 48
17 to 52 mixture in my hands of the Z to E. Then the
18 first operation that's done is recrystallization
19 from acetone, that is to precipitate, and which is
20 15-33-1P. And that has a ratio of Z to E of 33 to
21 67.

22 In other words, that is enriched in the

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

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

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

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

14 A NMR tends to be -- accurate isn't the
15 word -- sensitive to impurities, depending on what
16 they are, to impurities in approximately the
17 1 percent to 5 percent realm.

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

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

3 A I am.

4 Q What is limit of detection?

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

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

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

19 But the point is there -- according to
20 their advertisements, there could have been
21 0.0001 percent of impurity.

22 So nothing's absolutely pure, but

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

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

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

15 Withdrawn.

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

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

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

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

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

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

20 And going to the bottom on the left side,
21 sample 15-35-2P, I have indicated that that is a
22 100 percent (Z)-isomer.

1 So from all this, I certainly can -- I
2 know that I can detect 5 percent of an impurity.
3 And in other cases, I believe I can detect down to
4 1 percent impurity. So, bottom line, the limit of
5 detection for E and Z is probably about 1 percent.

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

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

10 Q The 15-35-2P sample that you just
11 mentioned in the bottom left of the figure on
12 Page 45 of 95 of your declaration, you said that's
13 100 percent pure?

14 A Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 A I don't think I've ever seen that in the
8 25 years -- well, more than that -- that I've
9 worked in this area, but theoretically it could
10 exist. I don't see it in the case of endoxifen.

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

12 A I'm sorry. Right. The other point I
13 wanted to make is these samples did not sit on a
14 shelf. These samples were stored either in a
15 freezer, which is at minus 20 degrees in my
16 laboratory, or in a refrigerator, which is at
17 4 degrees. All degrees that I mentioned are
18 Celsius degrees. So they were not stored at -- at
19 room temperature in a hot environment or anything
20 like that.

21 Q Okay.

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

1 other evidence I have is that I did store one
2 sample of pure (Z)-endoxifen in the freezer, minus
3 20 degrees, for one year, and reevaluated it, and
4 there was no change.

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

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

11 A No. It's in my notebook.

12 Q Okay. Where --

13 A So --

14 Q I'm sorry. Go ahead.

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

22 Q Is that in the pages of the lab notebook

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

5 A That's on Page 35 of my notebook.

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

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

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

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

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

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

19 Okay. Right. My notebook. There it is.

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

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

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

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

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

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

22 A Yeah. Apparently, it was an earlier copy

1 that didn't include that additional experiment.

2 Q And I think you mentioned that you --

3 A I --

4 Q I'm sorry. Go ahead.

5 A Yeah, I apologize for that omission.

6 Q And I think you mentioned some stability
7 testing discussed in your declaration. If you can
8 please turn to Paragraph 97 of your IPR

9 declaration. And that's on Page 58 of 95 using
10 the stamps in the bottom right, for the record.

11 A Okay. Paragraph 97, right?

12 Q Yes.

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

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

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

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

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

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

2 A Okay.

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

5 A You said Paragraph 96?

6 Q 94, please.

7 A Okay. Go ahead.

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

11 A Yes.

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

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

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

20 Q This is Page 53?

21 A Yeah, Page 53, three lines down.

22 Q Yes, I see that.

1 A So I probably can't say that any better
2 than I wrote. I'll just read this. I sealed
3 samples of (Z)-endoxifen under nitrogen in capped
4 vials inside Ziploc plastic bags. I kept one
5 sample of (Z)-endoxifen at 25 degrees centigrade,
6 60 percent relative humidity for ten days, and
7 another sample at 40 degrees and 75 relative --
8 percent relative humidity for ten days. Neither
9 sample indicated isomerization of Z to E after ten
10 days.

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

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

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

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

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

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

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

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

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

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

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

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

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

18 Q I see.

19 A And that was pure (Z)-endoxifen.

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

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

4 A Yes, with one clarification. When I say
5 one sample and another sample, it's the same
6 sample as (Z)-endoxifen. It's just -- what I'm
7 saying is I subjected -- maybe it's not written as
8 clearly as I could have, but I did two experiments
9 with the same sample, and -- and so one was
10 25 degrees, 60 percent, and the other on the
11 same -- on a batch of the same sample was
12 maintained at 40 degrees and 75 percent relative
13 humidity, both for ten days.

14 Q Those were consecutive experiments?

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

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

1 to your declaration, right?

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

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

12 Is that okay?

13 A Yeah.

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

18 Is that right?

19 A Yes.

20 Q What -- withdrawn.

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

1 what polymorphic form a molecule takes?

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

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

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

16 Q Okay.

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

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

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

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

9 Q What is a disappearing polymorph?

10 A What is it?

11 Q Yes.

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

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

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

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

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

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

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

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

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

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

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

16 Q Do you recall in Liu there's a discussion
17 of (Z)-endoxifen with an isometric purity of
18 99 percent?

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

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

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

3 Q Yeah.

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

7 Q Okay.

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

11 Actually, I have to search for it. Let's
12 see. It's in Paragraph 46. Six lines from the
13 bottom in Paragraph 46. As I say, I utilized NMR
14 to determine the ratios of (E)- to (Z)-endoxifen
15 through integration of the NMR signals at 3.85 and
16 4.01 ppm, respectively.

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

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

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

1 was Richardson.

2 Yeah. Paragraph 96.

3 Q Okay.

4 A I'm not sure it's an error. The -- in 96,
5 the first mention of Richardson is correct.

6 Richardson has numerous purification techniques.

7 But there should be another reference which --

8 which I believe is in the collection of documents

9 that -- that we both have, and crystallization --

10 the crystallization reference, additional

11 reference, and perhaps a better one, is

12 Wieckhusen. That's W-I-E-C-K-H-U-S-E-N.

13 Q Thank you.

14 Why don't we take a ten-minute break.

15 It's been over an hour.

16 A Okay.

17 Q And then when I come back, I'd like to

18 look at Exhibit 1003, which is the Liu reference

19 in the IPR.

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

21 MR. MILEA: Okay. Let's -- let's come

22 back at 11:25 Eastern.

1 (A recess was taken.)

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

4 BY MR. MILEA:

5 Q Welcome back, Doctor.

6 A Thank you.

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

9 Do you have that in front of you?

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

11 Q And for the record, that is Exhibit 1003,
12 1-0-0-3, in the IPR.

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

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

16 A The publication ending 651, right?

17 Q Yes.

18 A Okay. Got it.

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

21 A Yes, it is.

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

1 say?

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

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

8 A Okay.

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

11 Is that what you have?

12 A Can you repeat that? That's WO
13 2027/070651, right?

14 Q Yes.

15 A Yes.

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

18 Is that right?

19 A 2017.

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

22 A Yes.

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

4 A Yes.

5 Q Is -- do you see a description of Example
6 7 of Liu on your screen?

7 A Yes.

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

12 A Yes.

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

16 Do you see that?

17 A I think you meant to say isomeric.

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

20 A Yes, I see that.

21 Q What is HPLC analysis?

22 A Oh, HPLC, obviously, is an abbreviation,

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

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

7 A Yes.

8 Q Is that right?

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

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

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

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

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

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

3 Q Is NMR different than HPLC?

4 A Totally.

5 Q Can NMR report -- withdrawn.

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

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

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

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

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

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

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

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

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

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

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

1 sample with those reported by Atossa.

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

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

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

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

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

15 A Okay.

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

18 A Yes, certainly.

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

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

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

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

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

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

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

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

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

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

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

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

22 Q Okay. What scale would you call the

1 reactions that you ran in your lab?

2 A Well, I prefer to say quantitatively, for
3 example, that I worked on a scale originally --
4 in -- in the first step, a scale that was at
5 1/1000th the scale of Liu, just for -- to get some
6 preliminary results.

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

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

18 Q So is it -- withdrawn.

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

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

1 experiments?

2 A I would rather call it optimization. So
3 the first time that I did -- that I repeated the
4 first step in Liu, it appeared to me that the
5 reaction didn't go to completion, but nonetheless,
6 I did obtain the product, but it was only in the
7 13 percent yield. So I tried to increase that,
8 and I succeeded in doing that.

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

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

19 But the other thing is that, as I said, I
20 had a lot of starting material at the end of the
21 22 hours. So I think it -- we can look at the
22 notebook, but I think in that case, I increased

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

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

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

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

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

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

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

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

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

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

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

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

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

15 Q If you would have followed Liu as written
16 and not added the column chromatography step and
17 proceeded to the next example using whatever
18 material you wound up with at the end of Example
19 2, what would have been the consequence of that?

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

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

4 Q Sure, let's do that.

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

6 Q It's Paragraphs 62 through 64 --

7 A Yeah.

8 Q -- of Exhibit 1003.

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

14 Q It is -- I do see that.

15 A Oh, I see it. Yeah. Okay.

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

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

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

6 Does that answer your question?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 later examples of Liu?

2 A I think that's more or less correct.

3 Again, the purpose in my first preliminary
4 experiment was to isolate the apparent product and
5 prove that it was the product. Then I went on
6 with further experiments to basically vary the
7 temperature at which the reaction was performed.

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

16 I'm not sure --

17 Q I -- sorry. Go ahead.

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

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

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

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

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

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

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

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

7 A Yeah.

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

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

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

18 A Yes, absolutely.

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

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

5 Is that basically the question?

6 Q Let me re-ask it.

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

10 A Yes. Correct.

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

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

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

1 chromatography?

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

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

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

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

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

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

9 So even though Liu and I purified by
10 different methods, slightly different methods, and
11 Liu did not do chromatography, somehow he got
12 87 percent yield and 97 percent pure material.

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

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

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

1 impurities in mine after chromatography.

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

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

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

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

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

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

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

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

3 A Yeah.

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

7 Withdrawn.

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

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

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

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

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

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

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

1 So there's -- there's a spot in the middle
2 of doing reactions on, I don't know, maybe
3 100 milligrams to a gram that -- that is probably
4 the easiest to do.

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

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

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

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

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

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

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

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

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

20 Q When -- sorry.

21 A I'm sorry. Let me just continue.

22 Going back to the temperature control

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

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

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

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

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

1 least one of the reasons.

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

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

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

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

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

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

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

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

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

17 A They're the same thing.

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

22 A I'm sorry. Say that again.

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

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

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

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

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

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

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

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

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

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

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

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

4 A Yeah, and that column is called a
5 condenser.

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

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

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

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

19 A Yes.

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

1 results?

2 A Yes.

3 Q In what ways?

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

12 So let's just say that the boiling point
13 of the solvent is 80 degrees. If you immerse the
14 reaction vessel in a temperature bath that's at
15 80 degrees, the reaction won't quite get -- the
16 internal temperature of the reaction won't quite
17 get to 80 degrees. It would probably be, let's
18 say, 3 or 5 degrees -- very roughly, 3 or
19 5 degrees less than 80. In other words, 75, 77.

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

22 Q Did you say the rate of reaction?

1 A Yes.

2 Q What is the -- withdrawn.

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

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

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

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

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

1 the lower the temperature, the slower the rate?

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

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

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

10 A You said rate slower, correct?

11 Q Correct.

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

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

22 Q Would the impurity profile be different in

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

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

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

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

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

22 A Yeah. You could say that -- higher

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

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

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

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

17 Q You said that -- withdrawn.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 made to decrease the amount of solvent.

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

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

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

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

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

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

22 Q Okay. That's fine.

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

3 Q Sure. Let me try. Withdrawn.

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

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

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

14 Q And so the end results could possibly be
15 different?

16 A Yeah. They -- they could be. For
17 example, if X reacts with Y to produce Z,
18 frequently there would be a molar ratio of at
19 least 1 to 1, depending on the action. Let's say
20 1 to 1.

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

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

7 Q Would -- withdrawn.

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

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

14 Q Yes.

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

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

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

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

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

6 Q Would you generally -- withdrawn.

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

13 MR. MAHON: Object to form.

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

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

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

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

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

5 (A recess was taken.)

6 BY MR. MILEA:

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

11 A It -- it could, but I'm not aware that I
12 did that. In fact, my preliminary experiments --
13 just to ensure that I didn't make a mistake, my
14 preliminary experiments were done at precisely
15 1/1000th the scale of Liu's in Example 2, in Liu's
16 Example 2, and so I don't think any error was
17 made.

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

1 there.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Q Is that -- withdrawn.

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

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

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

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

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

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

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

22 A Okay.

1 Q What is crystal nucleation?

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

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

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

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

18 Q How so?

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

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

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

8 So there are different stages in the
9 process.

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

12 A Crystallization.

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

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

18 A Yes.

19 Q How so?

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

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

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

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

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

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

1 dissolve the material into the -- withdrawn.

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

5 A Yes, that's what I mean.

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

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

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

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

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

1 conclusion of the crystallization process?

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

8 Again, the tradeoff is yield versus
9 purity.

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

14 A Sure.

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

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

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

1 and that scratching causes you to get
2 crystallization?

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

11 Q Is stirring another way to induce
12 crystallization?

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

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

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

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

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

8 Q It's possible that it could, though?

9 A I don't know.

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

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

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

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

19 A Okay. Paragraph 61.

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

1 particularly remember that experiment because
2 4 degrees is the temperature of the refrigerator
3 in my lab, and I don't typically stir at 4 degrees
4 for 40 hours.

5 And so I recall putting the stirrer at --
6 a magnetic stirrer into my refrigerator with an
7 extension cord, so that's what I did. "That"
8 meaning cooled and stirred for 40 hours at
9 4 degrees. And this follows Liu.

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

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

15 A Yes.

16 Q What was that precipitate?

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

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

22 A Well, what I say is precipitate. There

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

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

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

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

22 Q Well, what's the significance of the fact

1 that it was just a small amount of precipitate?

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

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

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

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

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

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

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

10 MR. MAHON: Objection; form.

11 A Yes.

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

16 A Yes.

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

19 A No.

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

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

6 Q And just to be sure, you did not run NMR
7 on the small amount of precipitate that you
8 observed before you scratched the flask and added
9 24 more hours of stirring, right?

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

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

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

1 A Correct.

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

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

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

15 A Sure.

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

20 A Yeah, centrifuging is basically an
21 alternative to filtration.

22 Q And we talked about this, but column

1 chromatography is another way to purify?

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

9 Now you're talking about something totally
10 different.

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

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

19 So crystallization is a form of
20 purification. Generally, crystallization is a
21 form of purification, but purification is not
22 always a form of filtration or crystallization.

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

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

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

9 Q Right.

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

11 Q So there are types of --

12 A Most --

13 Q I'm sorry. Go ahead.

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

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

19 A Absolutely.

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

22 A As stated by Liu, when you have a mixture

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

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

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

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

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

1 crystalline precipitate.

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

4 A We say celite.

5 Q Okay. I'll say celite, then.

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

8 A Yes.

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

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

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

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

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

9 A Yeah.

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

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

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

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

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

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

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

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

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

1 precipitate, particularly if the precipitate is
2 fine particles.

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

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

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

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

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

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

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

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

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

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

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

18 Q Yes.

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

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

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

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

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

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

22 You'd have to do some calculations looking

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

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

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

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

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

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

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

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

9 Q Next --

10 A -- that I've worked with.

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

15 Did I get that right?

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

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

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

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

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

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

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

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

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

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

3 A I think you're asking about a suspension.

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

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

11 A Let me answer in a slightly different way.

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

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

22 Q With suspension, is it possible that the

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

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

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

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

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

1 discussing.

2 Q Do you consider a suspension -- withdrawn.

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

7 MR. MAHON: Objection; form.

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

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

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

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

8 Q Yes, take your time.

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

12 I'm looking -- excuse me.

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

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

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

1 A What exhibit number is that again?

2 Q 1033.

3 A Okay. I've got that open.

4 Q Okay. And I'm looking at the end of
5 Paragraph 71 of Exhibit 1033.

6 A Now I have a new problem. My scroll bar
7 has stopped working. So I'm going to have to --
8 I'll close PDF files and load that again.

9 Q Okay. And if it's helpful, you can look
10 at the Zoom. Ky has very helpfully put up the
11 purification scheme I want to talk about.

12 But if you want to scroll, you can
13 certainly reopen Acrobat.

14 A I'll try to do that during a break.

15 Okay. I think I got the one that he sent,
16 but -- that Ky sent, but I -- the scroll bar is
17 not working there either. But maybe -- maybe I'm
18 looking at the right pages. Above Paragraph 72?

19 Q Yes. Do you see a chart which is your
20 purification scheme?

21 A Yes.

22 Q So at the top of this, you see it says

1 Crude Endoxifen, right?

2 A Yes.

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

5 A Yes, it is.

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

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

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

19 A Yeah.

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

1 me just ask that. Withdrawn.

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

7 A Yes.

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

11 A Yes.

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

15 A Well, the 15-27-1?

16 Q Yes.

17 A Yes.

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

21 A Generally, they'd be called intermediates.

22 Q So you synthesized an intermediate in Liu

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

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

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

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

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

3 A Yes. To put that another way, this --
4 this chart, I believe, is an accurate
5 representation of what I did, and so all of the
6 notebook numbers are specified on this chart below
7 the first line, originated with the first sample,
8 15-27-1.

9 Q Okay. I think you said that the material
10 15-27-2 that you generated following some version
11 of Liu's Example 4 was essentially -- essentially
12 equivalent to 15-27-1; is that right?

13 A That's my recollection.

14 Q Do you remember how those materials
15 differed?

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

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

22 In your mind, is essentially equivalent

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

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

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

11 THE WITNESS: Fine with me.

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

14 (A recess was taken.)

15 BY MR. MILEA:

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

21 Do you have those documents, Doctor?

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

1 reopen Liu in a second.

2 '651, right?

3 Q Yes.

4 A Okay.

5 Q Please turn to Paragraph 62 of Liu.

6 A Okay.

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

9 A Right.

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

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

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

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

19 Q Okay.

20 A Go ahead.

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

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

2 A Paragraph?

3 Q 51.

4 A Okay.

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

9 A Yes.

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

13 A Yes.

14 Q Generally, what is the purpose of
15 compound 5?

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

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

1 intermediate.

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

7 A Yes.

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

14 A Yeah, I can do that.

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

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

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

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

7 Q Okay. And it says --

8 A Let me pull that with my note copy.

9 Yeah.

10 Q Are you --

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

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

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

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

21 A Yeah, it's the same thing.

22 Q Okay.

1 A Exactly.

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

6 A Yes.

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

11 Do you know what that says?

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

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

21 Two lines after that, it says, EX 2 times
22 1 over 1,000.

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

3 A Yes.

4 Q Okay. Then next to that, it says 30 to
5 75 degrees I.

6 Is that right?

7 A Yes.

8 Q What does that mean?

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

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

18 Do you see that?

19 A Yes.

20 Q And the first ingredient is ZnBr₂.

21 Is that zinc bromide?

22 A I'm going to correct, apparently,

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

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

8 A Okay. Thank you.

9 Q And so we can talk about that.

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

12 Q I had a fun weekend.

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

15 A Yeah.

16 Q Zinc bromide, is that $ZnBr_2$?

17 A Yes.

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

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

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

5 Q Okay.

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

8 Q Okay. And you just referred on the next
9 page to a drying set on page 80. Does that say --
10 it says oven dried at -- and I can't tell if it's
11 130 degrees or 230 degrees?

12 A That's a 2.

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

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

18 Can you please tell me what that says?

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

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

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

7 A Yes.

8 Q What is the significance of that?

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

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

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

21 Do you see that?

22 A Yes.

1 Q What is the significance of that?

2 A Not exothermic?

3 Q Yes.

4 A I believe that Liu states on the larger
5 scale that the reaction was exothermic, or it
6 implies that. So in my hands, reaction not
7 exothermic.

8 It's, in my opinion, important to note
9 whether a reaction was exothermic because a
10 severely exothermic reaction could get very hot
11 and get out of control, and you wouldn't -- you
12 wouldn't know necessarily the -- what the
13 temperature internally is, you know, without a --
14 although I -- continuing to the next couple words,
15 it says, stirred to 40 to 50 degrees internal, so
16 it did not get out of control, and it remained at
17 the stated temperature.

18 Q Why did you say that Liu either implied or
19 stated that its reaction -- withdrawn.

20 Why did you think Liu's reaction was
21 exothermic?

22 A Well, let's take a look. That would be

1 Example 2 of Liu.

2 Before I answer, I want to be sure here.

3 Q Sure. Take your time.

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

6 Q Yes. Go ahead.

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

11 So since room temperature, even though
12 it's not stated, it's probably about 20 to
13 25 degrees in Liu's lab, the reaction heats up to
14 50 degrees when the phosphorous tribromide is
15 added over two and a half hours. So I didn't have
16 to do that because my reaction was not exothermic.

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

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

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

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

10 Q Okay.

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

14 Q Okay. Earlier when we were starting to
15 talk about this example, I think you said that the
16 30 to 75 degrees up at the top of this page
17 indicated that you had performed the reaction in
18 that temperature range; is that right?

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

21 Q Is that indicating that the -- withdrawn.

22 Is that indicating that the internal

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

3 A Well, that's interesting. Unless I'm
4 missing something, I don't see anything on my --
5 on this page of my lab notebook that says
6 75 degrees. Wait, I think I see something.

7 Yeah. Okay. I did not make a mistake.
8 If you see the line that starts off with the date
9 7/18/23?

10 Q Yes.

11 A And then go down one line below that.

12 Q Okay.

13 A It says 3:45 -- by the way, that's the
14 time -- p.m. Then it says -- and it says, Then
15 75 degrees for 20 hours.

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

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

1 50 degrees internal temperature, that it was
2 mostly starting material by TLC.

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

7 So I raised the temperature to 75 degrees,
8 and TLC showed more product was -- and that -- the
9 TLC, by the way, is depicted at the very bottom.
10 The dots are -- with -- with captions that say,
11 for example, 50 degrees for one hour, 50 degrees
12 for two hours, 60 degrees for two hours,
13 75 degrees for 20 hours.

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

16 A Yes.

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

19 A Correct.

20 Q And fair -- so -- withdrawn.

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

1 to get a totally complete reaction following Liu
2 as written?

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

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

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

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

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

22 Was that also so you could see what the

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

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

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

15 MR. MAHON: Objection to form.

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

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

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

5 Another possibility that we kind of
6 alluded to was that even though I had zinc bromide
7 from a reputable source, it was possible that it
8 slightly decomposed. Again, water in it. And so
9 that's why I, on the next page, dried it at
10 235 degrees centigrade.

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

13 A It's well-known that zinc -- I don't want
14 to get, like, overly technical here, but zinc
15 bromide is acting kind of like an acid. It's
16 called a Lewis acid. We learned about this in
17 high school. And if there's water in there, then
18 there would be -- water would actually turn some
19 of that into zinc hydroxide, and it would
20 interfere with the reaction.

21 Q Would the water potentially turn into
22 hydrochloric acid as well?

1 A Hydrobromic acid.

2 Q Hydrobromic acid, you said?

3 A Yeah.

4 Q And you said that that could interfere
5 with the reaction?

6 A Yeah. I mean, I'd have to think about
7 this a little bit, but basically what's going on
8 in this reaction is one of the side products is
9 water, or -- because if you look at the reaction,
10 water is eliminated when these two starting
11 materials are put together.

12 So any water that creeps into the reaction
13 is not going to be good for it. I would -- I
14 would -- that was my hypothesis, and I think
15 that's -- generally, in this kind of reaction, the
16 use of Lewis acid, you want to make sure that
17 water is eliminated from -- from the starting
18 materials.

19 Q Was the zinc bromide that you purchased
20 anhydrous?

21 A Well, it was supposed to be. Yeah.

22 Q You --

1 A As I said, it does have a tendency to
2 absorb water.

3 Q Does it say somewhere on Page 79 that you
4 suspected there was water and that it was turning
5 into zinc hydroxide?

6 A No. And I don't usually note my
7 hypotheses, which may or may not be right, in my
8 notebook.

9 What I simply did was to repeat the
10 reaction on the next page using zinc bromide,
11 which was dried, and on PDR 3, which was the
12 scope.

13 Q Okay.

14 A So that, needless to say, is a shorthand
15 way of describing what my concerns were.

16 Q Okay. Going back to --

17 A And it worked. The yield was -- was
18 improved.

19 Q Okay. If we go back, please, to the
20 7/17/23 entry on Page 79, and I want to talk about
21 the last line of that entry before the 7/18 entry.
22 I think it starts with 22 hours.

1 Do you see that?

2 A Yes.

3 Q And then I think it says, the last three
4 words of that line, Hard to stir.

5 Is that right?

6 A Yes.

7 Q What is the significance of that?

8 A Basically, an observation. And it's also
9 perhaps a notation for me, if I do this in the
10 future, that particularly on a larger scale, it
11 might be advantageous to use mechanical stirring
12 rather than magnetic stirring.

13 Q If you look now in the 7/18/23 entry, the
14 fourth line of that entry, the second -- it looks
15 like the second word is 1K.

16 Do you see what I'm talking about?

17 A That's 2H.

18 Q 2H. Okay. What's the word before that?

19 A Stir.

20 Q Stir two hours.

21 Okay. And then later, I think it says,
22 initial oily PPT, which is precipitate; is that

1 right?

2 A Yes.

3 Q And then after that, I think it says, Most
4 dissolved except clumps and fine precipitate?

5 A Yes.

6 Q What is the significance of most of it
7 dissolving except for the clumps?

8 A Frankly, I don't know without further
9 testing. I don't know what the chemical
10 significance of that is. I just try to write --
11 write down my observations, particularly on ones
12 that are maybe unexpected or possibly significant.
13 But I -- I don't know what the -- I don't know
14 what the actual chemical significance of this is.

15 Q And if we go several lines down, there's a
16 line where most of it is blank, and if you go all
17 the way to the right, it says 15-20-1.

18 Do you see that?

19 A Yes.

20 Q And I believe below that is the
21 chromatography step that we discussed?

22 A Yes.

1 Q Okay. And then -- withdrawn.

2 That's the chromatography step that wasn't
3 in Liu but that you added, right?

4 A Yes. I added that so that I could
5 basically analyze what the TLC spots represented
6 by running NMR on the materials that I isolated by
7 chromatography.

8 Q Why did you want to do that analysis?

9 A I think I answered that before. Basically
10 so they would have a chromatographic standard of
11 the authentic material so that I could monitor the
12 progress of subsequent preliminary reactions or
13 the fine-level reaction that I did in this series
14 by TLC. So I --

15 Q And that you couldn't -- I'm sorry.

16 A So I would have an authentic sample of
17 material, authenticated by NMR, which I could then
18 use as a standard for TLC so that I would know
19 what the TLC was telling me.

20 Q So that you could adjust your experiments
21 accordingly to make sure that the TLC was matching
22 the chromatographic standard that you acquired?

1 A Yeah.

2 Q Okay.

3 A To put it a little differently, so that I
4 would know the interpretation of a TLC. In the
5 absence of -- in the absence of a standard, all I
6 can say is I started out with one spot of TLC, and
7 I ended up with a different spot, but I don't know
8 what either one is until I run the NMR.

9 Q And so adding that step was the only way
10 that you knew whether you were getting the same
11 results as Liu?

12 A Adding what step?

13 Q Adding the chromatography step was the
14 only way that you knew whether you were getting
15 the same results as Liu?

16 A It was the only way that I would know that
17 I was getting the same product from Example 2 as
18 Liu got.

19 Q Underneath that, down two lines, it looks
20 like SL.SIM. and unknown. I'm not sure I read
21 that right. Can you tell what that says?

22 A Yeah.

1 Q What is that?

2 A Let me go back up a couple lines.

3 Do you see where it says yellow band?

4 Q Yes.

5 A 40 milligrams. It turns out that the
6 product, the 40 milligrams represents a 13 percent
7 yield, and it says that it's an orange glass -- it
8 says it's siloed in chloroform, in small
9 parentheses, the NMR, I think it's in CD3OD, which
10 is -- I'll just say it's an NMR solvent, is okay,
11 and then aspect is okay.

12 Then there's an orange -- the next line,
13 orange band, 35 milligrams. Orange glass. Inside
14 ON CHCO3, NMR, and the same solvent as above,
15 shows slight starting material plus unknown
16 compound.

17 Q Is the unknown compound an impurity?

18 A It's -- it is a side product, but it's not
19 an impurity in 1A because it's separated
20 chromatographically from 1A.

21 Q Before it was separated, was it an
22 impurity?

1 A Yes.

2 Q And so adding this chromatography step
3 allows you to remove that impurity. Is that fair?

4 A Yes.

5 Q And had you not added the chromatography
6 step, would that impurity have been in the final
7 material that you made in Example 2?

8 A Apparently.

9 Q And then you would have used that final
10 material to perform Example 3?

11 A No. I would have -- as I said before, I
12 would have purified.

13 Q Okay.

14 A I purify -- I generally purify after I
15 reset, as I mentioned before. Otherwise, you'd go
16 through the entire synthesis and end up with an
17 inseparable mess.

18 Q Right. So the purification steps that you
19 added allowed you to avoid the problem of ending
20 up with an inseparable mess at the end of the
21 synthesis process; is that fair?

22 A Yes, but we're getting ahead of ourselves

1 because that hadn't really been accomplished until
2 I did this preliminary experiment under specific
3 conditions four times and then scaled it up for
4 the fifth time.

5 Q Okay. But the fifth time, you also added
6 this purification step?

7 A Yes.

8 And just to point out, Liu did not do
9 chromatography, but Liu precipitated the product
10 with methyl t-butyl ether, and that may have
11 gotten rid of some impurities.

12 Q You don't know what this impurity was,
13 right?

14 A In Liu's synthesis?

15 Q I -- on Page 79, this unknown impurity, it
16 was unknown, right? You didn't know what it was?

17 A Right. I mean, that's -- that's what it
18 says. It says there's slight starting material,
19 plus an unknown.

20 Q But you don't know whether Liu's
21 precipitating step would have gotten rid of this
22 unknown impurity; is that fair?

1 A Well, Liu says that he had material that
2 was determined to be 79 percent pure by HPLC --
3 I'm sorry. A little dyslexic there. 97 percent
4 pure by HPLC.

5 Q So there was a 3 percent impurity in Liu's
6 material?

7 A Yeah, which, by the way, for an
8 intermediate compound in a series, 3 percent
9 impurity is generally not something to be
10 concerned with.

11 Q Okay. Let's turn the page, please, and go
12 to Page 80, which I believe is your second attempt
13 at recreating Liu's Example 2; is that right?

14 A Yes.

15 Q And, again, this is at 1/1000th scale?

16 A Yes.

17 Q And here it says, up at the top, repeat:
18 50 to 75 degrees I.

19 A Yes.

20 Q Does that mean 50 to 70 degrees internal
21 temperature?

22 A Yes.

1 Q And before, you did 30 to 75 degrees in
2 your first attempt?

3 A Yes.

4 Q So you've now raised the lowest --
5 withdrawn.

6 So you've now raised the lower end of your
7 temperature range by 20 degrees Celsius?

8 A Yes.

9 Q And there's an entry, 7/24/23, and you're
10 discussing zinc bromide, and then all the way on
11 the right, it says oven dried, 230 degrees
12 Celsius?

13 A Yes.

14 Q And while we're talking about oven drying,
15 if you go all the way to the bottom, right above
16 your TLC diagram, it says, I believe, some product
17 and NGHCO_3 .

18 Right?

19 A NAHCO_3 .

20 Q NAHCO_3 . And then what are the words after
21 that?

22 A Well, there's an asterisk there that --

1 we'll see what that refers to, and it says some
2 product, and that's sodium bicarbonate layer after
3 the plus HCL. I think that means after the
4 addition of HCL, and extraction with FOCA, which
5 is methyl acetate.

6 Q Okay. Go back up to the July 24th, 2023,
7 entry. The third line says, heat 50 degrees
8 internal. What does it say after that.

9 A Again, that's the name of the stirrer,
10 Cimerac.

11 Q Okay.

12 A And the temperature of the Cimerac, the
13 bath -- that's what -- that's what the B is -- was
14 53 degrees, which gave an internal temperature of
15 50 degrees.

16 Q And then after that, you heated to
17 75 degrees?

18 A Yes.

19 Q If we go to the last line of that entry
20 right before the July 26th entry, do you see it
21 says, about halfway through that line, heat
22 55 degrees internal, 58 degrees bath, and then

1 heat 95?

2 A Yeah. On -- just a little bit shorthand.
3 I can understand it.

4 The Cimerac stirrer is also a heater, and
5 it has settings. So when you set it for 95, the
6 bath temperature is 58.

7 Q Okay. And then in the next line again,
8 heat to 75, and you obtained an orange clump
9 separate from orange fluid. And after that, you
10 note, contains most product.

11 Is that right?

12 A Yeah. I'm still thinking about your
13 previous question.

14 Yeah. I believe what I said is correct
15 about the meaning of the number 95 for 21 hours.
16 Yeah, because you can see -- yeah. You can see
17 that when the digits after the pound sign, the
18 number sign, increase, so the bath temperature
19 increases. So, again, that's just a way that I
20 know where to set the heater/stirrer in order to
21 achieve the required bath temperatures.

22 I'm sorry. You had another question?

1 Q The next line, the 7/26/23 entry talks
2 about heating to 75 degrees. And then, skipping
3 ahead, it says, orange clump separate from orange
4 fluid, parentheses, contains most product.

5 Is that right?

6 A Yes.

7 Q Are you saying that the orange fluid
8 contained most product or the orange clump?

9 A I admit it's a bit ambiguous, but since
10 the words "contained most product" are after
11 orange fluid, I believe that the orange fluid at
12 that point contained most of the product.

13 Q Did you know that the orange fluid
14 contained most of the product because of the TLC
15 results at the bottom of this page?

16 A As far as I can see -- okay.

17 Yeah, this is a little bit hard to
18 interpret, but on the TLC results at the very
19 bottom of the page, there is apparently a word
20 that says "clump," and it looks like the clump is
21 somewhat more enriched in the product than the
22 reaction itself. But I would -- I would be a

1 little hesitant with that conclusion.

2 Q Do you say that because there are more
3 dots in the TLC diagram at the bottom of the page?
4 How do you know that?

5 A Okay. The final product from this -- let
6 me sure that's right before I say anything. Yeah.
7 The final product on -- is the one that the TLC
8 results that's labeled -2, and that consists
9 mostly of the higher spot. So that's what --
10 that's what I'm looking for. That -- that shows
11 what the reaction is doing.

12 And so the clump looks like it has more of
13 that higher spot than the reaction at 75 degrees,
14 the TLC result to the left of that, that 75 --
15 that says 75 degrees for 1.5 hours.

16 It's not -- it's kind of qualitative. So
17 I -- I would not necessarily report that, and I
18 didn't report that in my actual write-up because
19 it's speculative.

20 Q Okay. And if we go to the July 26th,
21 2023, entry, three lines from the bottom of that
22 entry, I think it says stir clump in solution.

1 Is that right?

2 A Still clump -- still clump insoluble.

3 Q Oh, still clump insoluble. And that's
4 after some additional stirring that you did?

5 A That's what we call -- what we would call
6 the workup of the reaction, which is pouring the
7 reaction into ice water and stirring.

8 Q Okay. And then if we go to the July 27th,
9 2023, entry, three lines down toward the end of
10 the third line, I think it's referring to
11 chromatography, a particular medium?

12 A Yes. That's correct. It refers to
13 chromatography.

14 Q And that's, again, the purification step
15 you added that wasn't in Liu so that you could
16 remove impurities from your final product of
17 Example 2, right?

18 A It's both to remove impurities and to
19 determine what the yield is, because the objective
20 here is to increase the yield, which, by the way,
21 this did. So the yield here is 33 percent; the
22 yield on the previous page was 13 percent. So

1 it's more than doubled the yield.

2 Q Got it. And it says 33 percent yield on
3 the line after that?

4 A Yes.

5 Q Okay. Let's look at the next page,
6 please.

7 Is this your third attempt at recreating
8 Liu's Example 2?

9 A Yes.

10 Q And, again, here you're making some tweaks
11 to what's written in Liu?

12 A Yes.

13 Q And then if we look at the next page,
14 which is Page 82, is this your fourth attempt at
15 recreating Liu?

16 A I may -- if this is correct, I may have
17 misstated the number of repetitions of preliminary
18 experiments, because this is the fourth attempt,
19 but this is scaled up by a factor of 9.

20 So I revise what I said before. It looks
21 like I did three preliminary experiments and then
22 went to the experiment on the page we're currently

1 looking at.

2 Q If you go back to Page 81, do you see
3 there's an entry -- the page starts with
4 July 27th, 2023, and then there's another entry,
5 July 28th, 2023.

6 A Yeah. Of course. Okay. So I -- I revise
7 my revision.

8 Q So the experiment -- I'm sorry. Go ahead.

9 A So the one on -- on the bottom of this
10 page that's dated 7/28/23 is the fourth
11 preliminary repetition.

12 Q And so the experiment reported on Page 82
13 of the lab notebook is the fifth attempt at Liu
14 Example 2, right?

15 A Yes.

16 Q And does this fifth attempt -- withdrawn.

17 Does this fifth attempt at Liu Example 2
18 on Page 82 of your notebook have further tweaks to
19 it over your prior four attempts?

20 A I'd have to, you know, go through the text
21 word by word, but the major thing that I see is
22 here I say stirring mechanically, which is what I

1 hinted at before. That's the line below the one
2 stir at 1:30.

3 Q And stirring mechanically, that's
4 something you figured out you had to do based on
5 your four prior Liu attempts for Example 2?
6 Withdrawn.

7 A Yeah. That's what I was indicating -- the
8 text, like I said, it's difficult to stir is an
9 indication that mechanical stirring would be
10 superior, and --

11 Q Just --

12 A -- so, you know, based on the smallest
13 scale results, I chose mechanical stirring.

14 Q Okay. And just to make sure the record's
15 clear, because I started to withdraw my prior
16 question, I'm just going to ask it again, if
17 that's okay.

18 A Okay.

19 Q Stirring mechanically in the experiment on
20 Page 82 of your lab notebook, that's something you
21 figured out how to do based on your four prior
22 attempts to recreate Liu's Example 2?

1 A I take a little issue with the wording,
2 but I'll say that is something that I decided I
3 should do based on the preliminary experiments and
4 the fact that I was scaling up to a larger weight
5 and a larger volume, which would be even more
6 difficult to -- always is more difficult to stir
7 by magnetic means.

8 Q The July 28th, 2023, entry, the very last
9 line, there are four words. Can you read those,
10 please?

11 A The very last line?

12 Q Yes.

13 A I think what you're referring to is it
14 says, after high vacuum, parentheses, GEM.

15 Q What does that mean?

16 A GEM is the name -- I have a number of
17 vacuum pumps, and one of them is called GEM pump,
18 and that's -- they all have different
19 characteristics, and so I note the name of it.

20 Q What was the yield of your July 28th,
21 2023, experiment?

22 A It says 27 percent.

1 Q So it was less than your July 24th
2 experiment?

3 A Yeah. 27 versus 3.

4 Q What was the yield of your July 27th
5 experiment on Page 81?

6 A For some reason, it looks like I didn't
7 want to spend the time doing chromatography and
8 determining what the yield was.

9 Q Is that possible because it didn't work
10 and you could tell by TLC or some other way?

11 A That appears to be the case. I haven't
12 looked at this in two years, but the name of the
13 two compounds, that from the fluid is one-half,
14 and that from the clock is 1C with the appropriate
15 numbers before it indicating the notebook and the
16 page.

17 And then when you look at the TLC results,
18 yes. Neither one of those contains -- 1F contains
19 apparently none of the product, and 1C contains
20 only a small amount. That's why I didn't do
21 chromatography to purify.

22 Q So fair to say that your July 27th, 2023,

1 entry attempting to follow Liu Example 2 yielded
2 an incomplete reaction with no usable product?

3 A Little, little usable product. And I'm
4 not sure -- looking at it right now, I'm not sure
5 why that was the case, but I must have learned
6 from it.

7 Q You concluded while performing that
8 reaction that it wasn't actually worth the time to
9 even try to go on and figure out what the yield
10 was?

11 A Right. The TLC of the 1C fraction, if you
12 will, the 1C material, indicated that there was
13 some product, but mostly either starting material
14 or some side product.

15 So, no, it was not worth going forward.
16 And I'd have to look line by line to see why
17 this -- why this happened.

18 Q Fair to say that this July 27th, 2023,
19 attempt to follow Liu Example 2 was a failed
20 experiment?

21 A Well, it -- it was an experiment that gave
22 results, so it was a good experiment that way.

1 Practically speaking, it didn't provide much
2 product, but it did provide some.

3 Nonetheless, I must have changed the
4 procedure somewhat and ended up getting a much
5 better yield.

6 Q You mean from the -- withdrawn.

7 You mean you changed the procedure and
8 ended up getting a much better yield in a
9 subsequent experiment?

10 A Much better yield in subsequent
11 experiments, yes. The 27 percent yield at the
12 bottom of this page, and the 46 percent yield at
13 the bottom of the next page.

14 Q The 46 percent yield, that's the
15 experiment on Page 82 of your lab notebook?

16 A Yes.

17 Q And is this experiment, which is dated
18 August 1st, 2023, the experiment that you used to
19 generate the material that you then used in
20 Example 3?

21 A I believe so. That would be on the -- for
22 the next page -- well, actually, those things were

1 also done on a small scale, but it would -- yeah.
2 The -- that would be the material that I used
3 predominantly going forward, in part because
4 that's the material I had the most of.

5 I'm not sure if -- I could check, but I'm
6 not sure if I had some of the material from the
7 preliminary experiments or if I simply discarded
8 it. I'd have to look to make sure.

9 Q Let's talk about the experiment on
10 Page 82, please.

11 A Would you mind using the notebook numbers
12 that are at the top of the page?

13 Q Not at all. I'll say those, and I'll also
14 say the stamp numbers, if that's okay, just so the
15 record's clean.

16 A Okay.

17 Q So if we look at what is Page 23 of the
18 scan of your lab notebook, and that corresponds to
19 the stamp Page 82, we see an experiment performed
20 on August 1st, 2023, and the first line says,
21 scale up 15-22-2 times 9.

22 Do you see that?

1 A Yes.

2 Q What does that mean?

3 A It means what it says. Scale up the
4 experiment, which is on the previous page,
5 Page 22. That's the one that gave 27 percent
6 yield. Scaled it up. You know, all -- all
7 reagents were increased by a factor of 9.

8 Q Why did you increase all the reagents by a
9 factor of 9?

10 A I was attempting to get a quantity of
11 material 1 percent the weight of what Liu did so
12 that I could carry on with Liu at that appropriate
13 scale.

14 Q Why did you need to have a bigger scale
15 than you had previously been doing?

16 A Well, the previous experiments that we
17 discussed were just preliminary experiments, as I
18 mentioned, to be carried out on a small scale so
19 that I wouldn't waste material.

20 Now that I thought I had a reasonable
21 procedure, I could carry those out on -- on a
22 larger scale, and I wanted to ensure that I had

1 enough material to go through the rest of Liu's
2 procedure.

3 Q And in this experiment, you say that you
4 dried the zinc bromide at 230 degrees Celsius; is
5 that right?

6 A Yes.

7 Q And you were already using commercial
8 grade anhydrous zinc bromide?

9 A I was using commercial zinc bromide, which
10 I did not know if it actually had absorbed water
11 or not. So this was probably the same batch of
12 zinc bromide that I had dried at 230 degrees
13 before.

14 Does that make sense?

15 Q Yes. Was it commercial grade anhydrous
16 zinc bromide that you purchased, or you purchased
17 commercial grade zinc bromide without regard to
18 whether it was anhydrous?

19 A It was represented to be anhydrous.

20 Q Is drying at 230 degrees Celsius a
21 standard way to get an anhydrous material, or are
22 there other ways to do that?

1 A That would be the most common way. I
2 think if you look in Merck Index, it will
3 reiterate that that's how you can dry even hydrous
4 zinc bromide, but I'd have to check.

5 Q And, then, this reaction, unlike Liu's,
6 was not exothermic; is that right?

7 A That's what my notes say, yeah.

8 Q And then it says, the next line after the
9 1:30, I assume p.m., time, slowly heat to 68 to
10 70 degrees over one hour?

11 A Yes.

12 Q Is that right?

13 And so this is a change to Liu's
14 temperature, right?

15 A I believe Liu's temperature is 50 degrees.

16 Again, this is based on the results of my
17 preliminary experiments.

18 Q Right. So you figured out in your
19 preliminary experiments that certain aspects of
20 Liu wouldn't work as written, and so you modified
21 them so you could perform this experiment on
22 Page 82?

1 MR. MAHON: Objection; form.

2 A Yeah. I modified Liu's procedure,
3 particularly the temperature, because I found that
4 the lower temperature gave -- gave a poor yield.
5 That --

6 Q And that was because -- I'm sorry. Go
7 ahead.

8 A Maybe I'm not answering. And that may
9 have been because of the surface-to-volume ratio
10 issue where Liu was working on a larger volume.

11 Q And that issue was caused because of the
12 difference in scale of your experiment and Liu's
13 experiment?

14 A That's correct.

15 Q And then at the bottom of the August 1st,
16 2023, entry on the right, it says you obtained the
17 material 15-23-1.

18 A Yes.

19 Q And then there's an August 11th entry in
20 which it looks like you performed chromatography
21 on that material; is that right?

22 A That's right.

1 Q And, again, that was to remove impurities?

2 A Yes.

3 Q And then that yielded what you've written
4 here as 15-23-1A?

5 A Yes.

6 Q Is 15-23-1A the material that you then
7 used to attempt to recreate Liu's Example 3?

8 A Yes, but I -- I think on the next page --
9 let's see here -- yeah. On the next page, at
10 least for preliminary experiment, I used -- the
11 starting material was 15-21-2A. So it was an
12 equivalent material but from a different lot.

13 And then I -- I think subsequently --
14 yeah.

15 Q So on Page 83 onto 84, this is another
16 series of trial and error attempts at Liu's
17 Example 3 now; is that fair?

18 A Yes.

19 Q Okay.

20 A Just to -- to answer your question, if you
21 look at my notebook Page 25 --

22 Q I'm sorry. What page? I'm sorry. I know

1 you said you prefer the top -- the top numbers.

2 A Yes.

3 Q Yes. Page 25 on the top right, Page 84 on
4 the stamp. Yes, I'm there.

5 A Okay. About the fifth line, it says the
6 SM, starting material, was a mixture of 15-22-2A
7 plus 15-23-1A.

8 So -- and 9.99 grams total.

9 So there was that next step then on my
10 notebook Page 25 was conducted using a mixture of
11 those two, but it's going to be predominantly
12 15-23-1A, which is the scale-up that we just were
13 talking about.

14 Q I see. And does 15-22-2A come from the
15 July 28th, 2023, experiment on notebook Page 22?

16 A That's correct.

17 Q And so in order to perform Example 3 of
18 Liu, you took some material from one of your
19 earlier experiments and other material from a
20 different earlier experiment, both of which were
21 attempting to recreate Liu Example 2?

22 A That's correct, and both of which had the

1 same major spot by TLC. So I judged them based on
2 the history and the TLC to be essentially
3 equivalent.

4 Q Okay. Are there differences between the
5 July 28th, 2023, experiment on Page 22 of your lab
6 notebook and the August 1st, 2023, experiment on
7 Page 23 of your notebook other than the scale that
8 you used?

9 A I'd probably have to go through it line by
10 line, which would be tedious, but the major
11 difference I see is the stirring was mechanical on
12 notebook Page 23, and it was magnetic on Page 22.

13 Q Do you see the July 28th, 2023,
14 experiment, it says, stop with ice water after
15 four hours?

16 A I'm sorry. Where are you?

17 Q On Page 22 of your lab notebook, there's
18 the July 28th, 2023, entry, and it says, repeat
19 15-22-1, which is the --

20 A At the top.

21 Q And then it says, but stop with ice water
22 after four hours?

1 A Yes.

2 Q What is the significance of that?

3 A That's a cursory repetition, since I was
4 doing this over and over again, of the experiment
5 a couple lines above it where it says pour the
6 fluid onto ice water.

7 Q Okay. And in the July 27th, 2023,
8 experiment, about -- one, two, three, four -- five
9 lines down, it says, I think, heat 78 degrees
10 Celsius bath equals 75 degrees internal?

11 A Yeah.

12 Q And because in this July 2028th (sic)
13 experiment you're repeating this July 27th
14 experiment, you would have done that same heating
15 step to those same temperatures?

16 A Yes.

17 Q And in the July -- excuse me. Withdrawn.

18 In the August 1st, 2023, experiment,
19 you're heating to -- from 68 to 70 degrees
20 instead; is that right?

21 A That appears to be the case.

22 Q And so you're using some of the material

1 from your July 28th, 2023, experiment in which you
2 heated to 75 degrees internal and some of the
3 material from your August 1st, 2023, experiment,
4 in which you heated to 70 degrees internal, and
5 you're taking all of that -- or portions of that
6 and using it to attempt to recreate Example 3 as
7 shown on Page 25 of your lab notebook; is that
8 right?

9 A Yeah. I felt that I would do that because
10 the TLC on both those samples was approximately
11 the same. In other words, it was the same major
12 compound and approximately the same purity by TLC.

13 MR. MILEA: We've been going for about an
14 hour and 15 minutes. Would you like to take a
15 break?

16 THE WITNESS: Okay.

17 MR. MILEA: We can go off the record now.

18 (A recess was taken.)

19 BY MR. MILEA:

20 Q Let's look at your Example 3 experiments,
21 please, Doctor, and I'm now looking at Page 24 of
22 your lab notebook, which is Page 83 of 95 in

1 Exhibit 1003 in the IPR.

2 A Okay.

3 Q And it looks like on Pages 83 and 84,
4 you're again doing some trial and error testing of
5 Liu Example 3 this time; is that right?

6 A I would prefer to call it a preliminary
7 experiment.

8 Q And the purpose of the preliminary
9 experiment is to try to figure out what in Liu
10 works and what doesn't work so that you can modify
11 as appropriate and obtain the material that you
12 need to go on to the next steps?

13 A Yeah. I would -- I would call it to
14 confirm that the Liu procedure works on a small
15 scale before I take all the material that I spent
16 the effort to create in previous experiments. I
17 don't want to waste that material, so I would
18 perform them -- the next step on a small scale.
19 And that's what I would do pretty much every time
20 I do an experiment.

21 Q August 14th, 2023, looks like the first
22 version of Example 3 that you performed, and it

1 says you used 2.2 grams of zinc; is that right?

2 A Yes.

3 Q And what percentage scale-down was this
4 from Liu?

5 A I would have to pull up Liu.

6 Q Yeah. Please --

7 A Do you want --

8 Q Yeah, yeah. Please go ahead and do that,
9 and that's Exhibit 1003 in the IPR, and it's
10 Paragraph 65 of Liu.

11 A Okay. So just going by the zinc and
12 assuming I did everything else right, Liu uses
13 4.3 milligrams.

14 Is that what that says?

15 Q Yes.

16 A Okay. And I used 2.2 grams. So 2.2 -- I
17 should do it differently.

18 43 divided by -- it looks like it is
19 approximately a decrease in scale by 2000 fold.

20 Q Why did you choose a 2000 fold
21 approximately decrease in scale for Example 3?

22 A I would really have to speculate that

1 maybe the arithmetic was easy and I didn't want to
2 make a mistake.

3 Q In the August 14th --

4 A It looks like --

5 Q Sorry.

6 A As I look at the numbers, it looks like I
7 probably just divided all the quantities by 2000
8 because I felt that was an appropriate scale where
9 I would gain information but not waste a lot of
10 material.

11 I -- I think that's the answer, but I
12 can't recall on that.

13 Q You say gain information. What kind of
14 information?

15 A Well, you know, the same -- same kind of
16 information that it -- that I gained with -- in
17 Liu's Example 2. Does the reaction work, can I
18 isolate the product, what is the TLC of the
19 product, is it exothermic, is it not exothermic,
20 things like that. The normal things that one
21 would check for in a reaction.

22 Q The August 14th, 2023, entry on Page 24 of

1 your lab notebook, about four lines down, you note
2 that the reaction's exothermic.

3 A Yes.

4 Q Do you see that?

5 A Yes, I do.

6 Q What is the significance of that?

7 A Well, as I mentioned before, it's very
8 important to note if something's exothermic
9 because if it is majorly exothermic, significantly
10 exothermic on a small scale, it is going to be
11 very exothermic on a large scale and could get out
12 of control.

13 So there's precautions that one could take
14 to prevent that sort of situation. It is my
15 practice always to do -- almost always to do
16 reactions on a small scale first.

17 Q Is there less risk that the reaction
18 creates a lot of heat in a potentially dangerous
19 situation?

20 A No, it could create heat, it could
21 create -- not this one, but a reaction could
22 create a lot of gas, a lot of pressure, could be

1 explosive. So it's good to have a small problem
2 than a large disaster.

3 Q About two lines before the August 15th,
4 2023, entry, it says at the end of that line,
5 stirring impossible after about two hours.

6 A Yes.

7 Q What is the significance of the fact that
8 stirring was impossible after about two hours?

9 A Well, as I said before, it's mostly just
10 an observation. It could be important for scaling
11 up. If I don't note how it was stirred, chances
12 are that it was stirred magnetically, and that
13 when I scale it up -- we'll see if this is true or
14 not. When I scale it up, I might have wanted to
15 use mechanical stirring instead. We'll see if
16 that's true.

17 Q Okay. And then if we go to the
18 August 15th, 2023, reaction, it looks like --
19 there's a blank line, and then after that, it
20 looks like you're discussing chromatography again,
21 and then on the line after that, towards the end,
22 it says, something badly where -- try high vac GEM

1 on --

2 Can you -- do you know what that says?

3 A You are very brave for reading my --
4 attempting to read my handwriting.

5 Q My handwriting is terrible as well, so I
6 can empathize.

7 A Okay. The word is foams.

8 Q Foams?

9 A It foams badly when you try to -- it's not
10 good English, but when you try to high vac, when
11 you put it on a high vacuum. My shorthand.

12 Q With the GEM vacuum that you have?

13 A Yes. And so the significance of that is
14 to know that -- I mean, these are all things that
15 you learn with a preliminary experiment. You
16 asked why I would do a preliminary experiment.
17 This is why.

18 So if it foams badly, presumably I
19 prevented that from foaming -- prevented the
20 foaming from making me lose product, but that
21 would mean that when I do this again, I should use
22 an oversized flask so that I definitely don't lose

1 any material. As I recall, that's what I did.

2 Q Okay. And is this prior series of entries
3 on Page 24 of your lab notebook just one attempt
4 at recreating Liu Example 3?

5 A That's certainly what it looks like, yes.

6 Q Okay. And so let's please turn to the
7 next page of your lab notebook, which is Page 25,
8 or Page 84 of 95 if we're looking at the exhibit
9 stamp.

10 A Yep.

11 Q Is this entry -- withdrawn.

12 It looks like this is an August 17th,
13 2023, entry.

14 A Yes.

15 Q And it says repeat times 14.65 scale.

16 Is that indicating that you're re-doing
17 the experiment on the prior page, but you're
18 scaling it up by 14.65 times?

19 A That's correct.

20 Q Why did you choose 14.65 scale?

21 A That -- I think the idea was to use up
22 essentially all of the starting material, which is

1 C -- on the fifth line where it says SM indicates
2 the two blocks that were used in that 9.99 grams.
3 That's about how much I would have.

4 Q So that scale-up was just a function of
5 how much starting material you had and the goal
6 was to just use all of it?

7 A Yeah, the starting material being the
8 material from Liu Example 2.

9 Q Okay. And then two lines later, it says
10 in the last part of the line, stirring impossible
11 after five minutes.

12 A Yeah.

13 Q Do you see that?

14 A Yes.

15 Q Do you recall in Liu Example 3, Liu
16 discloses, in Paragraph 65, stirring for six
17 hours?

18 A Yes. It says the mixture was stirred and
19 heated at reflux for six hours.

20 Q And so one difference between what you did
21 and what Liu did was the time of stirring; is that
22 right?

1 A Not necessarily. I'm pretty careful at
2 writing down what I observed. Since I followed
3 this procedure with -- admittedly on a smaller
4 scale, I think Liu may have stirred initially, and
5 then stirring may have become impossible and he
6 didn't notice it or he didn't bother to write it
7 down. I think that's likely because the reaction
8 is what it is. In my hands, stirring quickly
9 becomes impossible, so I would think it's probably
10 the same thing for Liu, and that he failed to note
11 that.

12 Q So is it your testimony that Liu's
13 statement that the mixture was stirred and heated
14 at reflux for six hours a statement that Liu only
15 stirred for five minutes?

16 A I can only hypothesize, but based on my
17 results, I think that stirring would have been
18 very difficult or impossible in Liu's case also.

19 But keep in mind it looks like I actually
20 used magnetic stirring since I don't say
21 mechanical. So Liu may have had -- especially for
22 the large volume uses, he may have had a much more

1 powerful stirrer, mechanical stirrer, and maybe he
2 did. So I can't really say with certainty whether
3 Liu was able to stir for the entire time.

4 But I will note that -- if you have ever
5 heard the expression the proof is in the pudding,
6 let's see, I got at the end of this a 59 percent
7 yield, if you scroll down to the bottom of this
8 page, whereas Liu got a lower yield. I think it
9 was -- let's see -- you want to go -- okay. I'm
10 looking at -- I'm looking at Liu Paragraph 65, and
11 I want to go to Paragraph 66.

12 Can I control this or not? Okay. There
13 you go.

14 Okay. Liu obtained 644 grams.

15 Is this the -- this is Example 3. Yes.

16 Q Yes.

17 A And I think I calculated this, and it is
18 something like 37 percent yield, and I got a
19 59 percent yield.

20 So everything worked out. And, you know,
21 I got almost twice the yield as Liu.

22 Q Why would the yield of your experiment be

1 so much higher than the yield of Liu's experiment?

2 A Better laboratory procedure. No, I can
3 only speculate. One -- one -- I don't -- I don't
4 know. Maybe -- there are all sorts of possible
5 reasons, but I'm happy to say that I improved on
6 Liu's yield.

7 It really -- you know, you'd have to do
8 more experiments and deliberately try to get a
9 lower yield. It could be that -- one possibility
10 is that my chromatography in the previous step
11 removed other impurities that were still removed,
12 but I -- I don't know. I shouldn't even say that.

13 It's really speculation because Liu says
14 that HPLC indicated -- what was it, 97 percent
15 purity after Example 2? Sorry. I don't know.

16 Q What are some possible differences caused
17 by stirring a reaction on the one hand and not
18 stirring the same reaction on the other hand?

19 A Again, that's an interesting question. So
20 in my hands, it was stirrable initially, and then
21 it wasn't stirrable.

22 If everything was originally homogeneous,

1 then all the reacting molecules, the molecules
2 that react with one another, would be very close
3 together physically, and so it may not be
4 necessary to stir even though it would probably be
5 preferable.

6 So, you know, this -- I encountered this
7 occasionally where you just can't stir a reaction
8 after a certain period of time, but, again, the --
9 my results speak for themselves. I got a better
10 yield than Liu did.

11 But, you know, Liu got a usable yield, and
12 he continued with the synthesis.

13 Q Do you recall at this step that is in
14 Example 3 you used an argon atmosphere -- excuse
15 me, Liu used an argon atmosphere and you used a
16 nitrogen atmosphere?

17 A Yes.

18 Q Why did you choose to use a nitrogen
19 atmosphere instead of an argon atmosphere?

20 A They're basically interchangeable in
21 reactions like this. The idea is to keep air and
22 water vapor out of the reaction, and either argon

1 or nitrogen are the two commonly used choices to
2 accomplish that.

3 Q Where in your lab notebook, either on
4 Page 24 or 25, does it specify the atmosphere that
5 you used?

6 A I am not seeing it on Page 25. And
7 looking quickly, I don't see it on Page 24.

8 So when I was writing up the results for
9 my expert report, I probably -- I'm speculating a
10 little bit here, but I probably noticed that Liu
11 had said that he used an inert atmosphere of
12 argon, and I added that information, realizing
13 that I would definitely have carried it out under
14 an atmosphere, and I know that the inert gas that
15 I used was nitrogen.

16 Q On Page 25, does it give a sample number
17 for the final product that you generated in that
18 experiment?

19 A I believe so.

20 Q Do you see it anywhere? I'm just not
21 seeing it, to be candid.

22 A Okay. Bottom of Page 25, one line from

1 the bottom, it says -1AS -- nope. That's not it.

2 So two lines before that, the line that
3 begins, then in vacua remains yields 7.72 grams,
4 59 percent -- that means yield -- solid. On that
5 line, it says -1AP.

6 And that is the experiment number on
7 Page 25. So the full number would be 14. It's
8 the same on all these pages. It would be -- a lot
9 of times I don't have the notebook -- so it would
10 be 15-25-1AP.

11 Real quick, I may leave off the notebook
12 number, and I leave off the page number because
13 that's up at the top of the page. So that -- the
14 number I mentioned is the full notebook number.

15 Q Okay. What does --

16 A Just -- just to follow that through, then
17 the -- the TLC at the bottom of the page shows
18 that the TLC for that sample shows apparently
19 complete purity.

20 Q Okay. And combines after, it says 1AP, it
21 says 1AS.

22 What is 1AS?

1 A So there was a precipitate, apparently,
2 which was dried in air, and then vacua, et cetera,
3 melting point specified, and then one line from
4 the bottom, it says evaporate filtrate yields
5 622 milligrams, white semisolid, and it looks like
6 that's predominantly also the product by TLC, but
7 it's a little bit less pure than the precipitate.

8 The SSR, I discarded that.

9 Q Okay. If you look, please, at your
10 declaration on Page -- excuse me, Paragraph 55.
11 Do you see right before the NMR information, you
12 say that --

13 A I'm still -- I'm still trying to get to
14 it.

15 Q I'm sorry. I thought you were looking at
16 the screen. Let me know when you're there,
17 please.

18 A Is it on the screen? Okay.

19 You put it on the screen?

20 Q It should be in the Zoom window. At least
21 I'm seeing it in the Zoom window.

22 A And it's highlighted in blue?

1 Q Yes.

2 A Great. Okay. I'm there.

3 Q So do you see right before the NMR
4 information, it says that you generated a
5 compound -- a mixture of E and Z, compound 3 --
6 I'm not going to try to read that.

7 Do you see that?

8 A Yes.

9 Q And then after that, it says 7.72 grams,
10 15-25-1AS?

11 A Yes.

12 Q Is that the final product from your
13 Example 3 experiment?

14 A That's -- thank you for pointing that out.
15 That's a misprint. You can see four lines up, on
16 Page 25, that that should read 15-25-1AP, not AS.

17 Q Okay.

18 A I apologize there.

19 Q Okay. So the material that you generated
20 from Example 3 that you would then go on to use in
21 Example 4 is 15-25-1AP?

22 A Yes. And -- and so I copied that wrong.

1 So the melting point is -- is also incorrect. It
2 should be approximately 103 to 110. The NMR is
3 correct.

4 Q Okay. Let's talk about Example 4, please.

5 So on Page 26 and Page 27 of your
6 notebook, I believe that there are two versions of
7 Example 4; is that right?

8 A I believe that's correct.

9 Q And then if you could please turn to
10 Page 33 of your notebook.

11 A Yes.

12 Q It looks like this is another either
13 version or part of Example 4?

14 A Yeah. It identifies it as such at the
15 very top line.

16 Q Okay. What -- why are you reporting on
17 Example 4 on 85 -- excuse me, on 26 and 27 of your
18 notebook and then skipping ahead to Page 33 of
19 your notebook? Why are those separated like that?

20 A Yeah. Well, this is the order in which I
21 did the experiments. So if I have to dissect this
22 a little bit, the experiment on Page 26 is the

1 reaction of the material from Liu, Example 3, with
2 a methylol mean and ethanol to give a little
3 mixture of (E)- and (Z)-endoxifen.

4 That's at the top of my laboratory
5 notebook Page 25. And then there's a further
6 processing, according to Liu. That's toward the
7 bottom. And then things got kind of interesting.

8 So I obtained a precipitate, which is
9 designated 1X on this page, and a filtrate
10 designated as 1S. And I think we talked about
11 this before. This was -- this was where I used
12 vacuum filtration to try to isolate the
13 precipitate, but as it says, the filtration should
14 have been done at minus 10 degrees, but with the
15 small volume, that was difficult. It heated up,
16 and I obtained only 16 milligrams of precipitate.
17 So very little, I believe because it warmed up.

18 So that --

19 Q (Inaudible.)

20 A I'm sorry. What?

21 Q It warmed up on its own? I'm sorry. I
22 didn't mean to interrupt you.

1 A Yeah, it -- it warmed up on its own
2 rapidly, which on a larger scale would be less of
3 a problem. And so then I did another experiment
4 where I did centrifugation, a quick centrifugation
5 more reactively than I could do the filtration.

6 That is the first explanation for what's
7 happening on these intervening pages.

8 Q Just for the record --

9 A (Inaudible) experiments after that, which
10 are also on these intervening page.

11 Q Yes. And just for the record, Doctor, I
12 think at some point in your answer, you referred
13 to Notebook Page 25. You're looking at Page 26,
14 right?

15 A Yes.

16 Q Okay.

17 A Sorry I misstated.

18 Q And on Page 26, the August 17th, 2023,
19 entry says, starting material 15-246-1AP.

20 Is that right?

21 A Yeah.

22 Q So would that be the material that you

1 created in the experiments that are on Page 24 of
2 your lab notebook?

3 A Yeah.

4 Q And that was one of your dry runs at
5 Example 3?

6 A Yeah, preliminary experiment.

7 Q Okay. And so you used the information
8 from your Example 3 -- excuse me. Withdrawn.

9 You used the material from your Example 3
10 small-scale experiment in your Example 4
11 preliminary experiment; is that fair?

12 A Yes.

13 Q Okay. On Page 26, the August 21st, 2023,
14 entry, says -- it looks like it starts with
15 dissolve, and it goes on, and there's a second
16 line, and in parentheses, it looks like scratch.

17 Do you see that?

18 A Yes.

19 Q What does that refer to?

20 A Scratching the, I think, side of the flask
21 to induce crystallization.

22 Q Why did you do that?

1 A I don't think I had any previous data, so
2 probably just to ensure that there would be a
3 precipitate.

4 In other words, it can help but not hurt
5 anything.

6 Q On Page 27 of your lab notebook, it looks
7 like you're repeating that experiment.

8 A Yes, using the material from my Page 25,
9 rev 24.

10 Q Right. And the experiment you're
11 repeating is the one we were just talking about on
12 Page 26?

13 A Yes.

14 Q Can you tell from Page 27 whether you also
15 performed that scratching step?

16 A I don't see any scratching here.

17 Q Given that --

18 A But apparently it didn't need it, because
19 if I'm reading this correctly, at the bottom of --
20 of that first block of text before the blank line,
21 it says that I got an 82 percent yield.

22 Q Then given that it says repeat on the top

1 of Page 27, is that indicating that you did the
2 steps of the prior experiment? Or I guess --
3 withdrawn.

4 Why does it say repeat on the top of
5 Page 27?

6 A Two years later, I'm not certain why it
7 said repeat, but I -- it either means that I
8 repeated the reaction essentially as stated on the
9 previous page but a larger scale, or it could just
10 be an indication like, okay, I'm doing the same
11 reaction. The conditions might be a little bit
12 different. I -- I don't recall.

13 Q Do you see on Page 26 in the August 21st
14 entry, there's a line, it starts at indented, and
15 it looks like you're giving the melting point of
16 the (Z)-endoxifen that you produced?

17 A Okay. I'm going to have to disagree with
18 the summation of the question. I got a white
19 precipitate, 16 milligrams. I state what the
20 melting point was. I compare that to the
21 literature, and then I -- then on the indented
22 line, I say what the Z melting point was.

1 At this point, I didn't definitively know
2 whether I had the Z or the E or a mixture.

3 So then continuing on that line, I took
4 the NMR and DMSL -- that means -- technically,
5 DSMO, D6, and then I say that according to the
6 '263 patent, which I believe is Song, that I
7 obtained the (Z)-isomer, but according to '651, I
8 had the (E)-isomer.

9 So it was a bit confusing. It took some
10 time to decipher was going on. It looks like two
11 more references on the final two lines of Page 26.
12 So some people say it's -- most everybody except
13 Song says that the NMR indicates that it is a --
14 I've got to take it back.

15 The MCL reference, Z, and Journal of
16 Pharmaceutical and Biomedical Analysis apparently
17 says it's E. So which one is it?

18 It took me a while -- getting a little
19 ahead of myself, but eventually after carefully
20 reading all the other references, I relied on the
21 majority of references that said that that
22 material was the (E)-isomer, and I looked

1 particularly at Elkins, who carried out a more
2 sophisticated NMR experiment called an NOE
3 experiment, which rather decisively shows that the
4 material that was the precipitate here was E.

5 But I didn't know that for weeks. But on
6 the next page, we'll shed some light on what
7 happened.

8 Q Why did it take weeks for you to find out?

9 A Well, historically -- well, let's see.

10 It's not -- yeah, it's the page after this.

11 Page 28.

12 Okay. So the top line references patents,
13 the '651 is Liu publication, and the second one is
14 the '263, which I believe was Song.

15 And Song discloses the very simple
16 procedures for obtaining what he says is the
17 (Z)-isomer. Much simpler than Liu. One step,
18 recrystallized from acetone or methanol or
19 ethanol, isopropanol. Then I repeated those and I
20 got a nice crystalline material in most cases, but
21 still the question was, am I getting the
22 (E)-isomer or the (Z)-isomer?

1 And eventually I looked at the NOE results
2 and pulled the NMR results and concluded that Song
3 was -- assigned the isomers incorrectly.

4 Q And so your conclusion was what? That you
5 had the (Z)-isomer or the (E)-isomer?

6 A Okay. Two conclusions. One was that on
7 Song's NMR the assignments were incorrect, which,
8 by the way, Davies also agrees is the case. And
9 the second was that these simple
10 recrystallizations that Song used gave a
11 precipitate which was the (E)-isomer, which was
12 not desired.

13 So I had to then use the more elaborate
14 procedure of Liu.

15 Q Let's please look at Page 27, the
16 August 25th entry.

17 And am I right that the end result of the
18 first block of text before the blank line is that
19 you obtained a 52 to 48 mixture of (E)- to
20 (Z)-endoxifen?

21 A Yes, which, I believe, is identical to
22 Liu.

1 Q And that sample is designated 15-27-1?

2 A Yes.

3 Q And then it looks like after the blank
4 line, you say, repeat with starting material.

5 Do you see that?

6 A Yes.

7 Q And then what's the word after starting
8 material?

9 A Less pure, 15-24-1AS and 15-25-1AS.

10 Q Okay. And let's just take each of those
11 separately, please.

12 15-24-1AS, that would come from your
13 experiment on Page 24; is that right?

14 A Yes.

15 Q And that one is referring to -- withdrawn.

16 And on 24 is one of your versions of
17 Example 3 of Liu, right?

18 A I'm sorry. Say that again.

19 Q On Page 24 of your notebook, that is the
20 first attempt at Liu Example 3 that you performed?

21 A Yes.

22 Q And that one, if you look at the bottom, I

1 believe right above the NMR diagram, says, -1AS.

2 A Right above the TLC diagram.

3 Q I'm sorry. Right above the TLC diagram,
4 it says -- let me just re-ask it. Withdrawn.

5 On Page 83, right above the TLC diagram --
6 and this is lab notebook Page 24 -- it says 1AS.

7 A Yes.

8 Q And that would be sample 15-24-1AS?

9 A Correct.

10 Q And that is the sample with which you
11 experienced some bad foaming when you tried to
12 vacuum it?

13 A No.

14 Q What sample was the 1AS sample?

15 A That was the filtrate.

16 Q That was the filtrate. Okay. Where did
17 that come from?

18 A It starts on the line that begins with the
19 date 8/15/23.

20 Q Okay. And this material that you used for
21 stirring with heptane, that was not the material
22 with the foaming? That was something else?

1 A That was the material that foamed. That
2 would be the material that led to 1A. So it's a
3 step before that.

4 Q Okay. So just to make sure I get it all
5 in order, the material that foamed badly was 1A,
6 right?

7 A Yes.

8 Q And then 1A you stirred with heptane, and
9 that produced what?

10 A That produced a precipitate and filtrate,
11 and the -- I don't know if we discussed this. It
12 looks like on my copy, the -- the end of the
13 sample number is cut off. So the last line of the
14 text reads -1AS, and the last -- and the sample
15 number before that should be 15-24-1AP.

16 Q Okay.

17 A And you can see, by TLC, that they're both
18 same material and both totally pure to the extent
19 of TLC detection.

20 Q Now let's please go back to Page 27 of
21 your lab notebook, and we just talked about this
22 repeat with starting material less pure 15-24-1AS.

1 The other part of that starting material
2 is 15-25-1AS; is that right?

3 A Okay. You were -- you were kind of the
4 second paragraph of Page 27, right?

5 Q Yes.

6 A Okay. Yes, that's correct.

7 Q 15-25-1AS comes from the experiment you
8 performed on Page 25 of your lab notebook, right?

9 A Yes.

10 Q And two lines up from the bottom, it
11 refers to 1AS.

12 Do you see that? On Page 25.

13 I'm not sure if the court reporter heard
14 your answer.

15 A The answer is yes.

16 Q Okay. So if we go back, please, to
17 Page 27 of your lab notebook. The result of using
18 15-24-1AS and 15-25-1AS as your starting material
19 was what you've called 15-27-2, right?

20 A Correct.

21 Q Then if you could please skip ahead to
22 Page 33 of your lab notebook.

1 A Okay.

2 Q Is this where you were performing the
3 second part of Liu Example 4?

4 A Yes, meaning this is where I attempt to
5 separate the (E)- and -- or partially separate the
6 (E)- and (Z)-isomer.

7 Q If you look at your purification scheme at
8 Paragraph 71 of your report -- I'm sorry. That's
9 Paragraph 71 of Liu. Paragraph 71 of the
10 declaration.

11 A Yep.

12 Q Do you see your purification scheme at
13 Paragraph 71 of your declaration?

14 A I see it, but it's cut off at the bottom.

15 MR. MILEA: Can you please scroll down?
16 Thank you.

17 Q And so the step that we're talking about
18 on Page 33 of your lab notebook, that's the very
19 first step in this diagram which says acetone
20 recrystallization?

21 A Yes.

22 Q And in your purification scheme, you say

1 that you used 15-27-1, right?

2 A Yes.

3 Q And in --

4 A Now, in reality, I used predominantly
5 15-27-1, but I also combine that with 15-27-2
6 because the two were identical by TLC.

7 Q How do you know that you used
8 predominantly 15-27-1?

9 A Because going back to Page 27, I generated
10 over 7 grams of 15-27-1, and only 642 milligrams,
11 less than -- less than 1/10th the amount of
12 15-27-2.

13 And even -- even if I used all of 15-27-2,
14 that 642 milligrams, that would be less than half
15 of the amount indicated on the second line of my
16 lab notebook Page 33.

17 So strictly speaking, the top line on my
18 diagram on Paragraph 71 of my report perhaps
19 should read 15-27-1 plus 15-27-2, but I didn't
20 want to confuse things.

21 Q If you turn back, please, to Page 27 of
22 your lab notebook.

1 A I'm there, on that page.

2 Q Sorry. Do you see there's a 9/19/23
3 entry?

4 A What was the date, 9 --

5 Q I think it says September 19th, 2023, on
6 Page 27 of your lab notebook.

7 A Yes.

8 Q And then on the next page of your lab
9 notebook, Page 28, the first entry is
10 September 8th, 2023.

11 A Yes.

12 Q Why are the entries out of order there?

13 A Usually I'll put related information on
14 the same page. Usually that's in chronological
15 order.

16 In this case, I did the experiments above
17 starting on September 25th. I got the material
18 out, the material being 15-27-1, and then I wanted
19 to take an HPLC of that material.

20 Now, I have an HPLC in my lab, but it
21 takes -- it takes some time to set it up and find
22 the solvent system, inject the compounds.

1 So logic, so that's -- that's why it took
2 something like three weeks to run the HPLC. It's
3 on this page because logically it fits on this
4 page. It is the HPLC of 15-27-1, and so logically
5 it would not belong on the next page, that is
6 Page 28.

7 Q Why did you run HPLC of sample 15-27-1?

8 A 15-27-1, according to NMR, is 52 to
9 48 percent E and Z. Several of the prior art
10 citations describe HPLC using the rare and
11 elaborate column in which HPLC can separate the
12 E from the Z.

13 I wanted to use a regular available column
14 that I had at hand, which is what's referred to on
15 the second line where it says, column like a
16 sphere RP18. I go on to give the dimensions,
17 et cetera, the UV absorbance for the detector, and
18 I mention what the solvent is, and I found no
19 separation.

20 Then I used a different solvent, and it
21 says possible shoulder, meaning there didn't
22 really seem to be significant separation, if any.

1 What I was trying to do here, the
2 objective of this experiment was to see if I could
3 use this more readily available column and get
4 separation, analytical separation of the isomers
5 so that I wouldn't have to send each sample out
6 for IMR [sic], but that didn't succeed; so
7 therefore, all samples were analyzed for E and Z
8 content by NMR, which Dr. Davies acknowledges is a
9 legitimate way to determine the isomeric ratio.

10 Q I think you mentioned -- and I'm hoping we
11 can move through this quickly if my recollection
12 of what you mentioned is correct -- on Page 28 of
13 your lab notebook, were you trying to recreate
14 experiments from this WO 2012/050263 reference?

15 A That's Song, correct?

16 Q I'm not sure what the named inventor is on
17 that reference, but I can tell you.

18 Yes, that is the Song reference.

19 A Yeah.

20 Q As best as I can tell.

21 A This is -- yeah. I'm pretty sure it is.

22 I think I already answered that, but Song presents

1 a -- or discloses a way of separating the alleged
2 Z from E by recrystallizing from these solvents
3 acetone or methanol, methanol -- I think
4 isopropyl, maybe ethyl acetate.

5 Very seq-quant procedure. Unfortunately,
6 Song missed a sign of the E and Z NMR signals, and
7 it took me a while to figure that out, but it was
8 a great way of producing E, but that's not the
9 final product that we want.

10 So the experiment's on Page 28. I learned
11 something, but they weren't particularly useful
12 for producing the (Z)-isomer.

13 Q So all of Page 28 is your attempt at
14 performing Song's methods?

15 A I would have to check. I -- I think Song
16 reported all of these solvents, but I might
17 have -- I might have used one additional that I
18 came up with myself.

19 Q Let me ask it another way. Page 28, are
20 you attempting to recreate Liu at all on this
21 page?

22 A No.

1 Q And then on the top of Page 29, the
2 August 15th, 2023, entry, is that also Song?

3 A I don't recall it. I'd have to look at
4 Song, which I can easily do.

5 Q Is the August 15th, 2023, entry an attempt
6 at recreating Liu?

7 A Don't think so, because Liu, as you know,
8 recrystallizes from acetone, and then isopropyl
9 acetate, which this is, and then acetone again.

10 I can get Song right in front of me, if
11 you wish.

12 Q I'm not sure we need to look at Song, but
13 perhaps we can come back to that.

14 Can we please skip to Page 31 of your lab
15 notebook?

16 A Okay.

17 Q And up at the top of this page, it says
18 '651 Paragraph 70.

19 A Yes.

20 Q Is Paragraph 70 part of Liu's Example 4?

21 What are you doing here on Page 31 of your
22 lab notebook with respect to Liu Example 4?

1 A I missed the last part of your question.
2 What are we doing what?

3 Q What are you doing here on Page 31 of your
4 lab notebook with respect to Liu Example 4?

5 A I'd have to check to make sure, but it
6 looks like it is an attempt to reproduce Liu's
7 conditions from Paragraph 70.

8 Q Do you see you've used 15-27-1, which is
9 the material you generated from one of your
10 recreations of Liu Example 3?

11 A Yes.

12 Q And then if you skip to second -- the
13 second line from the blank line at the bottom, it
14 says, 80 percent Z plus impurities.

15 A Yep.

16 Q What is the significance of that?

17 A It is what it says. I got an 80/20
18 mixture of Z and E, so the 80 is great, and there
19 are impurities.

20 And this information would have been from
21 NMR.

22 Q What -- withdrawn.

1 Do you know why you generated those
2 impurities in this example?

3 A They were probably present in 15-27-1.
4 And, you know, I -- I can access that NMR and let
5 you know. My recollection is that the impurities
6 were relatively minor, but they would disappear
7 and be carried forward to additional
8 crystallization steps, and those impurities should
9 vanish, and I believe they did.

10 Q Okay. The second line from the very
11 bottom of this series of entries says, very little
12 precipitate after nine plus days.

13 What's the significance of that?

14 A Exactly what it says, that there wasn't
15 very much precipitate after nine days, and then
16 after an additional -- looks like two months,
17 there were some needles, but not much material was
18 obtained.

19 Q What does needles refer to?

20 A Needles is a term we use to describe a
21 precipitate that is probably crystalline, almost
22 certainly crystalline, and it is in the shape of

1 little crystals that kind of look like miniature
2 needles.

3 Q So what you found here in this attempted
4 recreation of Liu Example 4 was that you were
5 unable to get crystals?

6 A Not -- not very much precipitate.

7 Q And did Liu Example 4 get precipitate?

8 A I'd really have to check on -- check on
9 this, but -- yeah. If you put the flowchart back
10 up, that's the easiest way to decipher what's
11 going on. The -- that's from my Paragraph 71.

12 Right. Okay. So the experiment on
13 Page 31 didn't work very well. I could take a
14 look at this and try to explain why that is. I
15 don't know off the top of my head.

16 Then I figured out how to do the first --
17 I accessed recrystallization in a different way,
18 and that is indicated in the notebook
19 Page 15-33-1P.

20 Q Is this experiment on Page 31 an example
21 of a time that you tried to follow Liu's Example 4
22 but produced no usable material?

1 A I -- I'd have to go through this. I knew
2 at the time, but I don't know sitting here today
3 what happened here. We can figure it out if I
4 look at Page 33.

5 I think I deviated somewhat from Liu's
6 procedure, and that's why there was no
7 precipitate.

8 MR. MILEA: Why don't we take a ten-minute
9 break.

10 THE WITNESS: Okay.

11 MR. MILEA: Or more if others need it, but
12 we can go off the record.

13 (A recess was taken.)

14 BY MR. MILEA:

15 Q Doctor, can we please look at Page 30 of
16 your lab notebook?

17 Are you there on Page 30?

18 Doctor, do you have Page 30 of your lab
19 notebook?

20 A Yes.

21 Q Okay. Sorry. I couldn't hear you.

22 Is Page 30 one of your attempts to

1 recreate Liu Example 6?

2 A Based on the heading, it is recreation of
3 Paragraph 73.

4 Q And if you look at Paragraph 73 of Liu, do
5 you see that as part of Liu Example 6?

6 A I need to scroll down.

7 Could you scroll down a little so I can
8 take a look at 73? That was the example. I think
9 I saw that that was example -- yeah, well,
10 apparently it's Example 6. Yes.

11 Q Would you mind please just scrolling up to
12 the -- yeah. Thank you.

13 So Paragraph 73 of Liu is Example 6 of
14 Liu?

15 A Yes.

16 Yes, that's correct.

17 Q Okay. Thanks. And do you see the
18 October 12th, 2023, entry right at the top of
19 Page 30 of your lab notebook?

20 A Yeah.

21 Can you hear me okay?

22 Q Yeah, sorry. I'm looking at my notes, but

1 I did hear you. Thank you.

2 And in this entry, it looks like you're
3 combining several different samples from your
4 prior experiments; is that right?

5 A That's correct, yes.

6 Q And you report in the bottom of this entry
7 right before the blank line that you obtained
8 100 percent E.

9 Do you see that?

10 A Yes.

11 Q And 100 percent E is 100 percent
12 (E)-endoxifen?

13 A Yes.

14 Q Next to that, you write, XRPD not Form 1.

15 Do you see that?

16 A Yes.

17 Q How did you know that you had achieved not
18 Form 1 in this experiment?

19 A I just want to point out what the purpose
20 of the experiment is. If you look at the first
21 line, I combined those samples. All of those
22 samples were (E)-endoxifen precipitates, and then

1 I re-crystalized -- what I'm doing in this little
2 paragraph that follows is recrystallizing those
3 from refluxing isopropyl acetate.

4 And then the one that you referred to, I
5 had 100 percent E. So there was purification
6 achieved. I get crystalline material, and I
7 submitted that for SRPA, and the result did not
8 match that for Form 1, and the reason for that is
9 that this was recrystallized from isopropyl
10 acetate. In order to get Form 1, blue
11 recrystallizes -- well, I'm sorry. What's the
12 word that you used? Delete that.

13 This is not Form 1. This is -- there's
14 another one that my verbiage applied to. In this
15 case, I got 100 percent E, and E is never Form 1.
16 Z can be Form 1.

17 Q Were you expecting to get 100 percent E
18 from this experiment?

19 A Yeah, I think so. I sort it off as E
20 precipitates and recrystallizes, and so I would
21 expect, you know, recrystallization of E would
22 give E.

1 Q What is the purpose of this experiment on
2 Page 30 of your lab notebook?

3 A That's a good question. I can't be
4 certain in retrospect. Well, actually --
5 actually, looking at this for a second, I think I
6 know what I'm doing.

7 This material on the -- on the first
8 paragraph of Page 30 is the precipitate which was
9 100 percent E, is called 15-30-1P, and then that
10 is the material used in the second step where it
11 says 10/16/23.

12 So that was refluxed with isopropyl
13 acetate, was stirring for ten hours, cooled to
14 30 degrees, et cetera, and without going through
15 the whole thing, but the bottom line at the end of
16 that experiment was that I got 68 percent E, which
17 is to say 68 to 32 percent E to Z.

18 So what this experiment shows or confirms
19 is what Liu states, which is that if you treat the
20 (E)-isomer with refluxing isopropyl acetate, you
21 get isomerization to a mixture of Z and E. That's
22 the purpose of this experiment.

1 Q Where does Liu say that?

2 A Certainly in his disclosure where he talks
3 about isomerization. He says that -- as I recall,
4 he says that you can print the (E)-isomer with
5 resolving solvent, and I think he gives several
6 different solvent examples, and it isomerizes.

7 Furthermore, I think if you go to
8 Example 8. You want to scroll down?

9 Q I don't believe there's an Example 8.

10 A You're right. Okay. Then there's a
11 heading actually above this that says something
12 like isomerization and recrystallization of the
13 (Z)-isomer. So scroll up, please.

14 Q Is it the Example 6 heading you're
15 thinking of? Right there at the bottom of that
16 page.

17 A Oh, there it is. Yes. And so you'll see,
18 I think, in the paragraph that starts on the next
19 page -- yeah. Endoxifen, there's a ratio of E to
20 Z, 70/30, suspended isopropyl acetate, heated at
21 85 degrees for two hours, the E to Z ratio is
22 determined to be 1 to 1.

1 So there's that -- the example shows what
2 I summarized.

3 Q And so this is one of your attempts at
4 performing Example 6 of Liu?

5 A Yes.

6 Q And going back to the October 12th, 2023,
7 entry, where it says XRPD not Form 1 --

8 A Yep.

9 Q -- how did you know it wasn't Form 1?

10 A I submitted the samples to Steve Miller at
11 H and M. He ran the XRPD, and it was distinct
12 from Form 1.

13 Q How was that reported to you?

14 A He sent the -- he sent all the data that
15 he normally sends, which included the -- what's
16 called the diffractogram. That's kind of like --
17 looks kind of like a spectrum, and then he sends
18 also the crude data, which is recorded in degrees
19 and intensity. It's a whole long table.

20 It's generally, for me, most instructive
21 to look at the diffractogram, the visual display.

22 Q Are those data that you discussed anywhere

1 in your declaration?

2 A Probably not because it doesn't prove
3 anything. It just proves that the (E)-isomer
4 isn't Form 1, which you wouldn't expect it to be.

5 Q Is the end result of your experiments on
6 Page 30 the 4S sample at the bottom?

7 A Yep.

8 Go ahead.

9 Q Well, before we go to that, I have a
10 couple more questions about this October 12th,
11 2023, entry.

12 Why did you decide to send it for XRPD
13 analysis?

14 A I -- you know, I can only speculate on --
15 that perhaps I wanted to be sure that I got my NMR
16 assignments correct.

17 If the material that I believe --
18 everything's an experiment. If I -- if I
19 suspected the material that was 100 percent E was
20 actually misassigned to 100 percent Z, if it had
21 come back as being Form 1, I would have had to
22 rethink everything that I did.

1 Does that -- does that make sense to you?

2 Q I think I understand. So you were worried
3 that perhaps your results were wrong and you
4 wanted to check to make sure they were not at this
5 point?

6 A Right. It was just an additional
7 reassurance, because as you can imagine with all
8 the contradictory NMR information from the
9 different references, there was some chance
10 that -- that Liu's example -- Liu's assignment of
11 Z and E could possibly be wrong, and this
12 experiment was -- where I said was not Form B
13 [sic] is actually reassuring.

14 I think I -- I think I made these --
15 that's not Form 1. I think I said something else
16 by mistake.

17 Q Thank you. I believe you said Form B.

18 A Yeah. So, correct. Correct.

19 Q If you can please turn to Page 34 of your
20 lab notebook.

21 A Okay.

22 Q And up at the top -- wait. Excuse me one

1 second.

2 Please turn to Page 32. I'm sorry.

3 And do you see up at the top an entry for
4 October 24th, 2023?

5 A Yes.

6 Q And then here you're dissolving the 4S
7 material that you got from your work on Page 30
8 that we were just discussing; is that right?

9 A Yes.

10 Q And what are you attempting to do here on
11 this page?

12 A I'm attempting to -- let me take a look at
13 Page 30 to see what's there.

14 Okay. Compound, which is 15-30-4S was
15 used in the procedure that we're discussing, that
16 material is an 78 to 22 percent mixture of Z
17 and E.

18 In other words, it's rich in Z, but it's
19 not -- it's not a sufficient purity. So,
20 therefore, it was recrystallized from isopropyl
21 acetate, and that gave -- on the top of -- on the
22 top of Page 32, that gave 97 percent of pure Z.

1 That is 97 to 3 Z to E.

2 Q I'm sorry.

3 A So that -- that was submitted -- that was
4 before XRPD, and that was also not Form 1, even
5 though it was 97 percent pure Z.

6 Now, I guess I'll -- I'll just beg the
7 question, if that's the right word, why is it not
8 Form 1? Because it was recrystallized through
9 isopropyl acetate rather than acetone. What Liu
10 teaches is that in order to get Form 1, you must
11 recrystallize from acetone.

12 And just proceeding, logically, go to the
13 next line, the next experiment performed --
14 performed on 10/24/23, basically it was
15 recrystallized from acetone, and I got now the
16 sample that is 1532-2P, and that is Form 1.

17 So, again, recrystallizing from acetone
18 gives you Form 1; recrystallizing from isopropyl
19 acetate gives you a different form.

20 Q And the October -- withdrawn.

21 In the first October 24th, 2023, entry,
22 what were you attempting to do?

1 A I guess I was attempting to see if the
2 recrystallization from isopropyl acetate would
3 increase the purity that is the Z content, which
4 it did, and also wanted to determine whether the
5 crystals that were formed would be Form 1 or not
6 Form 1, and they were not Form 1.

7 Q Why did you want to know that?

8 A I guess to just understand the system,
9 what was going on, and how one could obtain the
10 Form 1 sample. So I was -- I guess you could say
11 I was purposefully deviating from Liu. That's my
12 recollection.

13 Q And were you -- other than changing the
14 acetone to isopropyl alcohol [sic] in this first
15 entry on October 24th on Page 32, did you make any
16 other changes to Liu's procedures?

17 MR. MAHON: Objection to form.

18 A The first line says IPR OAC. That's not
19 isopropanol.

20 Q I'm sorry. Isopropyl acetate, thank you.
21 So let me -- let me re-ask the question.

22 The first -- withdrawn.

1 The first entry on Page 32 of your lab
2 notebook says that you dissolved 15-30-4S in
3 isopropyl acetate; is that right?

4 A Yes.

5 Q And that it was refluxing?

6 A Reflux.

7 Q Okay. Was this a modified version of Liu
8 Example 7 that you were performing in this first
9 entry on Page 32 of your lab notebook?

10 MR. MAHON: Form.

11 A Reading it today, it doesn't look like it.
12 Paragraph 76 is a recrystallization from acetone,
13 whereas I recrystallized from isopropyl acetate in
14 this particular experiment.

15 Q Other than the change from acetone to
16 isopropyl acetate in this experiment, were you
17 attempting to reproduce Liu Example 7?

18 A I'd have to look carefully, but since the
19 solvent is different, it doesn't even matter if
20 everything else is the same.

21 Q Do you see in the left column of Page 32
22 under the 10/24/23 date in the first entry, it

1 says, reference 6510054?

2 A Yes. As I said, you've looked at my lab
3 notebook more recently than I have. So, yes,
4 let's go to Paragraph 54 of --

5 Q Liu?

6 A Liu, the Liu patent -- Liu publication.

7 I think he gives -- he gives some -- it's
8 right at the end. You may have to scroll down.

9 Yeah. So in Paragraph 54, he says, in
10 some embodiments, the third solvent is isopropyl
11 acetate.

12 If that means -- I'd have to go through
13 this whole thing, but if that means that the final
14 solvent that was used was isopropyl acetate, then,
15 in fact, I was attempting to reproduce
16 Paragraph 54 as I understood it.

17 That did not give Form 1.

18 Q Do you know what third solvent in
19 Paragraph 54 Liu is referring to?

20 A That's defined in the paragraphs above
21 where he says the first solvent can be chosen
22 from -- and it gives a list, and it could be a

1 second solvent, and it gives a list, and then he
2 says sometimes there's a third solvent, and the
3 solvent can be another list, and here he's
4 refining that, narrowing it to saying in some
5 embodiments, the third solvent is isopropyl
6 acetate.

7 So that was what I was following thinking,
8 well, maybe that will work.

9 Q Is the third solvent referring to a
10 solvent that's supposed to be used in Liu's
11 example seven, in the third step of example seven?

12 A You'd have to read the paragraphs and the
13 disclosure very carefully in order to be sure of
14 what that refers to. I think it's what I just
15 said. It's a very long paragraph, which defines
16 the first, second, and third solvent.

17 You could scroll up there, if you'd like.

18 MR, MILEA: Yes, please. Please do scroll
19 up.

20 Q And, Doctor, please see if you can answer
21 that question by reading Liu.

22 A I'm looking for a long paragraph. I'm not

1 reading every word. Just looking for a long
2 paragraph. Probably before that.

3 Q Perhaps Paragraph 26?

4 A Yeah, okay. This is the area.

5 So here in Paragraph 26, it's talking
6 about the second solvent, and it's a long
7 paragraph.

8 Then logically after that somewhere it
9 would define what the third solvent is. I think
10 it's before that.

11 And before any of this, he would define
12 what the first solvent is. It would be -- it
13 would be before this. It's before that big --
14 okay.

15 So this is Paragraph -- what number was
16 that? 21, I think.

17 Q It may -- it may be helpful if we look at
18 Paragraph 46.

19 A Wow, there's even a fourth step, but I'm
20 not sure that that is the fourth solvent.

21 Frankly, what Liu is doing here is he's
22 taking the examples that he actually carried out,

1 which we've been discussing, and I think he's
2 disclosing options beyond -- I guess the word is
3 his teaching alternatives which could be
4 considered.

5 Q I see. So Paragraph 46 of Liu is a
6 different embodiment than Example 6 of Liu?

7 A Without reading it carefully, my
8 recollection is that 46 is -- now, I'm not even --
9 reading this now, from my recollection,
10 Paragraph 46 would be a broadening teaching beyond
11 the examples --

12 Q Okay. So it's not --

13 A -- the examples that were recorded. I'm
14 sure he did other experiments that he did not
15 report.

16 Q Paragraph 46, then, is just a different
17 procedure than Example 6; is that fair?

18 A I guess I'd have to read it carefully.
19 Could you scroll up so I can see all of
20 Paragraph 46?

21 It's that long? Okay. Could you
22 unhighlight it, please? Thank you.

1 Okay. Got it. No. Paragraph 46 is
2 actually very important. It's not -- what I may
3 have said about it is -- is -- previously is
4 incorrect.

5 As he says, this is a -- another step, a
6 fourth step which involves isomerizing -- what he
7 says here is isomerizing the (E)-endoxifen to a
8 mixture of E and Z, which he says at the bottom of
9 that 46 to (E)-endoxifen -- sorry -- (E)- to
10 (Z)-endoxifen of approximately 1 to 1, which is to
11 say approximately 50/50.

12 So this is -- this is actually very
13 important in the process. I -- Liu reports -- Liu
14 discloses, and I confirmed, that it's pretty easy
15 to get a highly enriched sample of the
16 (E)-endoxifen which is free of other impurities,
17 and what Liu is teaching in 46 is that you can
18 take that material that's essentially pure (E)-
19 with very few impurities, reflux that in
20 isopropyl -- well, does he say isopropyl acetate?
21 That's what he means.

22 Reflux that in a solvent, and isomerize

1 the E to partially Z. And then what he doesn't
2 say here yet is that then you can crystallize out
3 the Z, ideally from acetone, and get Form 1 of
4 the -- of the Z iso.

5 And that -- all of this is I think best
6 illustrated in the flowchart that I presented.

7 Q Okay. Just so I understand, are you
8 saying Paragraph 46 is a separate experiment than
9 Example 6?

10 A It's -- I think we just saw that it is in
11 Example 6 in the portion that's entitled,
12 essentially, isomerization and recrystallization
13 of (Z)-endoxifen. It's the one we just saw.

14 Do you recall that?

15 Q Are you referring to Paragraph 73 or 74 of
16 Liu?

17 A Probably. Let's scroll down.

18 So it's not Example 7. It must be
19 Example 6. Which -- which paragraph number did
20 you say?

21 Q 73 and 74.

22 A Okay. Yeah. Yeah, it says here

1 endoxifen, suspended in isopropyl acetate, heated
2 to 85 degrees for two hours, whereas in
3 Paragraph 46, I think he mentions up to four
4 hours.

5 Q So in Paragraph 46 is a different way --
6 withdrawn.

7 Paragraph 46 is an exemplary embodiment in
8 Liu; is that fair?

9 A I'm not quite sure of the legal
10 terminology, but if I say it in layman's terms, 73
11 gives you an actual procedure, which in the end is
12 48 percent (Z)-isomer, I believe. No, sorry.
13 73 percent Z.

14 So it's 73 to 27. So it's highly enriched
15 in Z.

16 So that's fair, 73. Again, it gives an
17 actual procedure for an isomerizing so that you
18 get enrichment in (Z)-isomer.

19 Paragraph -- what was it, 40 --

20 Q 46.

21 A -- 46 is a general disclosure of how this
22 could be done. It doesn't -- it doesn't give the

1 quantities. It gives a range of times, et cetera.
2 That's the difference between the two, but
3 they're -- the general procedure is the same.

4 Q So Paragraph 46 gives different times and
5 different temperatures -- withdrawn.

6 Is Example 6 a specific way of doing the
7 general procedure described in Paragraph 46?

8 A I think that's fair.

9 Q And Paragraph 46 is describing alternative
10 ways that one might perform the isomerizing
11 procedure of Liu?

12 A I'd word it a little differently. It
13 gives a range of conditions in Paragraph 73. It
14 gives precise conditions.

15 Q And some of the conditions in Paragraph 46
16 are different than those in Paragraph 73, right?

17 A Well, I'd have to look at them side by
18 side, but as I recall, Paragraph 46, is it?

19 Q Yes.

20 A Paragraph 46, for example, says -- I think
21 says one to four hours.

22 Q .5 to four hours.

1 A Okay. So it's a range, whereas
2 Paragraph 76, was it?

3 Q 73.

4 A Okay. Too many numbers. 73 says for two
5 hours, right?

6 Q Yes.

7 A Yeah. So it's more specific, and it gives
8 the exact amount of endoxifen and the ratio. It
9 gives the details.

10 Paragraph 43, is that the other one?

11 Q 46.

12 A Okay. I'm going to write these down, if
13 you don't mind.

14 Q Okay.

15 A It's 46 and 73, right?

16 Q Yes.

17 A Okay. So 73 gives -- gives the exact
18 quantities, volumes, temperature, time. 43 is
19 broader. It gives a range of temperatures. It
20 gives how rapid cooling can be, very broad range.
21 Where did the -- where did the hours go on
22 Paragraph 43?

1 Q Paragraph 46 you mean, right?

2 A No wonder. Okay. Sorry. Yeah.

3 Let me -- let me start that analysis all
4 over in case I made a mistake.

5 So the process in 46 is described as an
6 isomerization step, and it gives the ratio of the
7 starting mixture of E and Z, and it says that you
8 heat between 60 and 100 degrees.

9 And in contrast, in Paragraph 73, it's the
10 boiling point of isopropyl acetate, which is
11 89 degrees. So it falls within this range.

12 Paragraph 46 says 0.5 to four hours, and
13 Paragraph 73, I believe, says two hours. So,
14 again, it's midway between the range here.

15 Q So the ranges in Paragraph 46 are broader
16 than the specific values in Paragraph 73, right?

17 A Yes, as is, in my experience, typical in
18 patents.

19 Q And so it's possible to follow
20 Paragraph 46 without following Paragraph 73?

21 A It would be possible literally to do so.
22 One would have to do experiments to see what that

1 gave you, because the only -- to my knowledge, the
2 only experimental result about what you get is in
3 Paragraph 73.

4 Q Right. But you could, for example,
5 following Paragraph 46, use a temperature of
6 60 degrees and a time of .5 hours, and that would
7 be a different experiment than was disclosed in
8 Paragraph 73, right?

9 A Yes.

10 Q Okay. I want to look at the second entry
11 on Page 32 of your lab notebook, please.

12 A Okay.

13 Q And this one, it looks like you're now
14 dissolving a sample 15-30-3P in refluxing acetone.

15 Is that right?

16 A Yes.

17 Q Is this -- withdrawn.

18 What example of Liu are you attempting to
19 follow here?

20 A Well, first, it's really much easier with
21 the flowchart, but if you don't want to do -- if
22 you do want to do that, that would be great.

1 Q Well, I'm happy to look at the flowchart.
2 It's a lot of flipping back and forth, which I was
3 trying to avoid, but I want to make this as easy
4 as possible for you.

5 So we can look at the flowchart, and
6 that's Paragraph 71 of your declaration.

7 A Yes. Okay. Great. So the experiment
8 you're asking about is the generation of -- I
9 believe of 15-30 -- no. You're asking me about
10 15-32-2P, right?

11 Q Yes.

12 A Okay. That's not on here. That's not on
13 the flowchart because even though it generated
14 Form 1, the purity -- the ratio of Z to E was 88
15 to 12, which is below the 90 percent that is
16 specified by Atossa.

17 But it did -- did get Form 1, and I'm
18 certain that if I recrystallized this again from
19 acetone that I would still get Form 1 and a higher
20 percentage of Z than 88 percent.

21 That's -- that's why this is,
22 unfortunately, not -- well, to prevent confusion,

1 that's why it's not on this flowchart.

2 Q What example of Liu were you trying to
3 follow here?

4 A In which experiment?

5 MR. MAHON: Objection; form.

6 Q In the second -- in the second entry on
7 Page 32.

8 MR. MAHON: Objection; form.

9 A I guess that brings us back to the
10 notebook. I'd have to look at what went into this
11 step.

12 There was a lot of experimentation that I
13 performed in preliminary experiments and didn't
14 include them in this flowchart because they only
15 confuse them, is my opinion. But -- okay.

16 So if you look at Page 30 of my
17 notebook -- we already looked at that. So I get
18 on 15-30-1P is essentially pure E, then I reflux
19 that with isopropyl acetate for ten hours. We
20 discussed that. I get a mixture Z and E,
21 predominantly E. I take that, I dissolve it in
22 acetone, refluxing, cool, and now I get a

1 precipitate that's 78 -- we talked about this --
2 78 percent. So let's say 78 to 22 Z to E, and
3 that is the material that is 15-30-3P, and that's
4 the material that was used on Page 32. So there I
5 recrystallize that material from acetone and get
6 Form 1.

7 So this would be a reproduction of -- of
8 Liu's procedure.

9 Q So Page 30 was a reproduction of Liu
10 Example 6, right?

11 A Yes, that's correct.

12 Q And then you put that material, and on
13 Page 32 in the second entry, you reflux that in
14 acetone pursuant to Liu's example seven; is that
15 right?

16 A I think that might still be 6. Want to
17 scroll down?

18 Q So if we look at Paragraph 73 of Liu,
19 which is part of Example 6, it just says that the
20 material was suspended in isopropyl acetate that
21 was heated at 85 degrees for two hours.

22 And what you did in example -- excuse me,

1 in the second entry of -- on Page 32 was dissolve
2 material in refluxing acetone, right?

3 A That's correct. So we have to find --
4 maybe -- it looks like that would be example
5 seven, if you want to --

6 Q Okay.

7 A -- scroll up. Yeah, Paragraph 76.

8 Q And would dissolving something in
9 refluxing material be the same thing as suspending
10 it in hot material?

11 A What -- what are you referring to in terms
12 of hot?

13 Q So in paragraph --

14 A Hang on --

15 Q I'm sorry.

16 A Hang on for a second. So, wait. I know
17 that this is complex, following my notebook and my
18 handwriting, but we were talking about the origin
19 of sample 15-32-2P, and that was created by
20 refluxing in acetone and then cooling.

21 So I'm comparing that to the percentage or
22 two of Paragraph 76, which is refluxing in

1 acetone.

2 Q And I was -- I was looking at
3 Paragraph 73, just to make sure I understand all
4 the differences between the October 24th entry and
5 this part of Example 6, because I think you
6 testified that it wasn't recreating Example 6, and
7 I wanted to just understand the differences.

8 So in the October 24th, 2023, entry, you
9 said you dissolved this material in refluxing
10 acetone, right?

11 A Yes.

12 Q And in Example 6, Liu is saying that
13 material was suspended. So that's one difference,
14 right? You dissolved the material in the
15 October 24th entry, and Liu suspended it in
16 Paragraph 73. Is that a difference?

17 A I think you have to understand that
18 this -- this whole thing is a process, and Liu is
19 explaining how to get pure (Z)-isomer, and there
20 are at least three steps which are actually in
21 that flowchart that we're looking at.

22 There's first a -- I would say a

1 preliminary recrystallization from acetone,
2 followed by a recrystallization and sometimes
3 isomerization, optionalized isomerization from hot
4 or refluxing isopropyl acetate, followed by a
5 recrystallization from acetone.

6 So I know it seems a little complicated,
7 but that's -- that's what it is. So you're
8 confusing this isopropyl acetate step with the
9 acetone step.

10 Q I see. But just focusing on the
11 suspending versus dissolving, are those important
12 differences?

13 A Well, maybe, maybe not, but it's a
14 different -- it's a different step of
15 purification.

16 Q Okay. So you're saying that the second
17 entry on Page 32 is an attempt to perform Liu's
18 example seven, recrystallization procedure, which
19 is in Paragraph 76 of Liu?

20 A Correct.

21 Q Okay. So what you found in performing
22 Liu's example seven recrystallization procedure,

1 you got (Z)-endoxifen, which was 88 percent pure,
2 right?

3 MR. MAHON: Objection; form.

4 A Yes. 88 percent Z, 22 percent E, Form 1.

5 Q How did you know it was Form 1?

6 A As before, I think -- the only way I ever
7 know anything is Form 1 or not Form 1 is by
8 submitting it to H and M for XRPD.

9 Q And how were those results reported to
10 you?

11 A The same as before. Diffractogram and a
12 list of the peaks by degree and the intensity.

13 As I said before, the diffractogram, which
14 is a visual portrayal, is easier for me to
15 visualize than the numerical tables, but the
16 numerical tables are more precise, but if you --
17 if you look at the figure of the diffractograms,
18 you can see at a glance that the Form 1 that I
19 obtained corresponds precisely through the Form 1
20 that's recorded in -- or disclosed in the two
21 (inaudible).

22 If you'd like to see what that looks like,

1 you could scroll down to find that in this report,
2 my report.

3 Q Just to be clear, these specific
4 diffractograms that you reference in the
5 October 24th entry, those are not in your report,
6 right?

7 A That would -- let's see. One is and one
8 isn't. The one that's not Form 1, I saw no reason
9 to report. The one that -- both samples were
10 submitted at the same time. I would have those
11 diffractograms, if you'd like.

12 Q Is it in your declaration, or you just
13 have that in your files?

14 A I would -- I would have that at least on
15 my computer.

16 Q Okay. It's not in the declaration that
17 you submitted?

18 A But you -- sorry to cut you off. No, not
19 in the declaration because the fact that a
20 different procedure gave something that was not
21 Form 1 was not really relevant to whether Liu was
22 operative, and getting Form 1 but with only

1 88 percent purity, I felt wasn't -- didn't justify
2 reporting.

3 But, you know, it's in my notebook, and
4 what it shows is that the experiment of
5 recrystallizing for an acetone worked pretty well,
6 but I thought I could do better, and I did.

7 Q Got it. So one of the times you followed
8 Liu, you got the 88 percent Z at Form 1, and then
9 another time you followed Liu, you got -- I think
10 you said 100 percent or 93 percent, depending on
11 which experiment of Form 1; is that right?

12 MR. MAHON: Objection; form.

13 A Yeah, 93 to 94 percent purity, in another
14 case no detectable E. So approximately
15 100 percent Z.

16 Q So the three times you filed Liu's example
17 seven, all three times you got Form 1 of
18 (Z)-endoxifen, one of the times it was 88 percent
19 pure, one of the times it was 93 or 94 percent
20 pure, and one of the times it was 100 percent
21 pure; is that correct?

22 MR. MAHON: Objection to form.

1 A I think that's correct.

2 Q I want to turn to Example 6, please.

3 Example 6 of Liu, that, I believe, as we
4 discussed, is the isomerization of (E)- and
5 (Z)-endoxifen mixture?

6 A Yes.

7 Q Where does Liu say to use the material
8 from Example 6 in example seven as you've done?

9 A Let's take a look at example seven, and
10 while -- while trying to keep Example 6 on there,
11 if that's possible.

12 Okay. So the first sentence under example
13 seven reads -- is that 5018 grams?

14 Q 5013.

15 A Okay.

16 Q That's what I see.

17 A Okay. 5013 grams. Does it say
18 approximately 30 to 70 E to Z ratio?

19 Q Yes.

20 A So it's enriched in Z.

21 Now, where did that -- the bulk of
22 material come from?

1 Okay. In Paragraph 74, you see 69 percent
2 Z content. So that -- that fits. Right above
3 that, I see 71 percent Z content. And at the
4 bottom, it said -- of 74, it says, the total
5 amount is 2348 grams.

6 I think -- I think elsewhere there's
7 another number that is in the 2000 region.

8 Q That was Example 5 of Liu, which is
9 Paragraph 72.

10 A That's --

11 Q 2666 grams?

12 A Yeah, that's great.

13 Q And I just added them together, and it's
14 5014. Them being the 2348 from Example 6?

15 A Yeah.

16 Q So is what you're saying Liu example seven
17 combines the materials from Example 5 and
18 Example 6?

19 A It looks like it, and you'll notice that
20 the E to Z ratio is on the order of 30 to 70.
21 Sometimes a little higher, sometimes a little
22 lower.

1 So I guess in his example he doesn't say,
2 but you have to figure out where the -- where the
3 material came from that he used in the next step.
4 I think we just figured that out.

5 Q Okay. And so --

6 A And let me -- let me rephrase that.

7 I believe I figured that out back when I
8 was trying to reproduce Liu a couple years ago,
9 but we re-figured it out.

10 Q Okay. Let's look at Liu Example 6. And
11 so Paragraph 73 of Liu says that in Example 6,
12 endoxifen was suspended in isopropyl acetate. The
13 suspension was heated --

14 A Which -- which paragraph?

15 Q I'm sorry, Paragraph 73 of Liu.

16 A Okay. Great.

17 Go ahead.

18 Q It says the endoxifen was suspended in
19 isopropyl acetate, and the suspension was heated
20 at 85 degrees for two hours.

21 Do you see that?

22 A Yes.

1 Q And then let's look at Page 34 of your lab
2 notebook, please.

3 A Okay.

4 Q And do you see there's an entry -- I
5 believe the date is January 26th, 2024, about
6 halfway down the page?

7 A Yep.

8 Q And it looks like it says Example 6,
9 Paragraph 73 through 74.

10 A Yes.

11 Q And do you see it says dissolve 15-34-1P
12 in refluxing isopropyl acetate?

13 A Yes.

14 Q And we just looked at Liu 70 --
15 Paragraph 73, and that said that endoxifen was
16 suspended in isopropyl acetate that was heated at
17 85 degrees.

18 Do you recall that?

19 A Yeah.

20 Q And so Liu, on the one hand, is saying to
21 suspend this material in hot isopropyl acetate,
22 and you, on the other hand, dissolved material in

1 refluxing isopropyl acetate; is that right?

2 MR. MAHON: Objection; form.

3 A I think this is the question that you were
4 asking, like, 15 minutes ago, and we finally got
5 to it.

6 So Paragraph 73 says suspend at
7 85 degrees. I say dissolve at reflux.

8 So, first of all, the boiling point of
9 isopropyl acetate is 88 degrees. That, first of
10 all, is not materially just different than
11 85 degrees. It wouldn't make any difference, that
12 3-degree difference.

13 Secondly, it's actually more likely that
14 Liu was at 88 degrees, because it's easy to
15 maintain the reflux temperature, more difficult to
16 accurately maintain 85-degree internal
17 temperature. So that's -- that's the temperature.
18 The temperature difference is, in my opinion,
19 immaterial.

20 Then there's the question of suspension
21 versus dissolution. I'm just recording what I
22 saw. I saw that all the material dissolved. If

1 Liu is saying that almost all the material
2 dissolved but some of it didn't, I -- based on my
3 results, I would take that to be what he probably
4 means. And, again, that wouldn't make any
5 difference.

6 The reason that wouldn't make any
7 difference is that the -- if the isomerization
8 only occurs on the material that is in solution,
9 on the endoxifen that is in solution, which I
10 think would be the case, it's going to -- the
11 material that sits in solution will be in
12 equilibrium with whatever precipitate there is,
13 and eventually it will all be subjected to
14 isomerization.

15 Q So --

16 A So the bottom line is -- I'm sorry. That
17 was a long -- a long response, but the bottom line
18 is 73, Paragraph 73 is totally consistent with the
19 isomerization that I performed on January 26th,
20 2024.

21 Q So is it your testimony that when Liu says
22 85 degrees Celsius, he means 88 degrees Celsius?

1 A I would -- I would suspect so.

2 Q Is that a mistake in Liu?

3 A I can only speculate on, you know, did
4 he -- did he have an internal thermometer? Was he
5 measuring, you know, right at the center? I -- I
6 don't know. I'm just saying it's more likely that
7 he meant 88 degrees refluxing, and that's what I
8 took it to mean, and that's why I refluxed.

9 Q Would acetone be refluxing at 85 degrees
10 Celsius?

11 A No.

12 Q You'd be able to see that it wasn't,
13 right?

14 A Well, let me rephrase that. The boiling
15 point of acetone, which is the reflux temperature,
16 I believe, is 65 degrees. So at 85 degrees,
17 acetone -- it can't -- it can't generally go to a
18 temperature higher than its boiling point unless
19 it's pressurized, which it's not.

20 So if you heated acetone to a bath
21 temperature of 85 degrees, which is not what this
22 is implying, but if you did that, the internal

1 temperature would still be the boiling point of
2 acetone, which is 65 degrees.

3 Q I'm sorry. I misspoke. I meant isopropyl
4 acetate. So let me -- let me re-ask that.

5 So is isopropyl acetate refluxing at
6 85 degrees Celsius?

7 A That is below its boiling point, so I
8 would say no.

9 Q And regardless of where your thermometer
10 was, you'd be able to see that it wasn't boiling,
11 right?

12 A Well, you know, it's like cooking.
13 They'll say -- sometimes on the recipes they'll
14 say vigorously boiling. If you were for some
15 reason right at 88 degrees, it might be difficult
16 to see it, bath temperature. Might be difficult
17 to see that it's refluxing.

18 If the bath temperature got to be, say, 10
19 degrees above the reflux temperature, that'd be
20 95 degrees. In this case, you should definitely
21 see refluxing.

22 Q Right. And he specified 85 degrees, not

1 88 degrees, correct?

2 A Yeah.

3 Q And he's also --

4 A The bottom line for me is that there's --
5 there's a difference between my interpretation and
6 what Liu strictly wrote.

7 Q Are you saying what Liu strictly wrote?

8 THE REPORTER: I think we lost the
9 witness.

10 MR. MILEA: Dr. Bihovsky, are you there?
11 Maybe we can go off the record.

12 (A recess was taken.)

13 BY MR. MILEA:

14 Q So this --

15 A I got cut off. I think the bottom line is
16 that I was saying that there's not a significant
17 difference between what Liu lays out in
18 Paragraph 73 and the experiment that I did.

19 Q But there is a difference; is that fair?

20 A There appears to be a difference, but I
21 don't think it's of any significance.

22 Q Okay. And then the other difference we

1 were talking about between what you did and what
2 Liu did was that Liu created a suspension in his
3 Example 6 and you dissolved the material in
4 Example 6 as reported on Page 34 of your lab
5 notebook; is that right?

6 MR. MAHON: Objection; form.

7 A So I -- I wouldn't say that I dissolved.
8 I just reported what I observed, which was that
9 when I put the material into isopropyl acetate, as
10 far as I could see, there was complete
11 dissolution.

12 Apparently Liu observed a suspension. So
13 some material apparently in Liu's case was in
14 suspension. But as I already stated, I don't
15 think that's of any significance for the reasons
16 that I went into before.

17 Again, the proof is in what you get out of
18 it, and on -- in the flowchart, I show that I
19 obtained (Z)-endoxifen with a purity of greater
20 than 90 percent.

21 Q Is it possible that in -- withdrawn.

22 So you -- you observed that all of your

1 material in Example 6 dissolved, right?

2 A Yes.

3 Q And Liu says that he observed that not all
4 of his material dissolved and some of it was
5 suspended, right?

6 MR. MAHON: Objection; form.

7 A That -- that seems to be what -- what Liu
8 is describing, that is consistent with the
9 suspension.

10 Q And is it possible that different
11 proportions of -- withdrawn.

12 And so in Liu's Example 6 mixture, which
13 was a suspension, is it possible that there was
14 some undissolved (Z)-endoxifen.

15 A Again, that's possible, but I don't think
16 that would change the result, and the -- my -- my
17 assumption is proven by the fact that the
18 isomerization worked in Liu's hands and also in my
19 hands.

20 Q And is it possible that in Liu's Example 6
21 mixture, which was a suspension, that the
22 undissolved material was (E)-endoxifen?

1 A It would have to be either E or Z. I -- I
2 would -- I would be pretty sure that it was either
3 E or Z or a mixture of the two that was not fully
4 dissolved.

5 Q And is it possible that whatever the
6 undissolved material was that Liu observed in his
7 Example 6, that that undissolved material seeded
8 the crystallization process and increased the
9 formation of either the (Z)-endoxifen or the
10 (E)-endoxifen in Liu's example?

11 A We're talking about Paragraph 73, right?

12 Q Yes.

13 A Well, in about the fourth line, he says
14 that the mixture was cooled, that the mother
15 liquor contained the (Z)-isomer, but he also says
16 that the crystals were E, preferentially E. I
17 don't think he gives a ratio.

18 So I don't know. It's possible that the
19 suspension was E. It's possible that the
20 suspension was caused by mixture of E and Z.
21 There's no data in Paragraph 73 to -- to tell, and
22 I don't think it really makes much difference

1 because in the end, he obtains a good yield of the
2 (Z)-isomer, 48 percent, and its Z content is
3 73 percent, which is an improvement.

4 Q And is it possible that suspended Z --
5 withdrawn.

6 Is it possible that there was some
7 (Z)-isomer suspended in Liu's mixture in Example 6
8 that seeded the crystallization in Example 6, and
9 wound up producing more (Z)-isomer than would have
10 otherwise been produced?

11 A I think we know from other data from --
12 both from Liu and other sources that the
13 (Z)-isomer is more soluble in most solvents,
14 including isopropyl acetate. Z is more soluble
15 than E.

16 So if -- if -- if anything, it's -- I'm
17 speculating, but it's more likely that the
18 suspension, if any, was caused by the (E)-isomer,
19 and it's -- it's -- as I've said, it's also likely
20 that any suspended (E)-isomer would actually be
21 converted or isomerized to a large extent to the
22 (Z)-isomer, and that the whole thing would become

1 soluble as the isomerization continued.

2 That is not what Paragraph 73 implies, but
3 that would require the person that did the
4 experiment to look at the -- look for evidence of
5 suspension at the beginning of the isomerization
6 and after two hours.

7 And also remember that however they heated
8 this material, it says two hours, but the mixture
9 would have taken a long time to cool, so the two
10 hours is actually, in practice, longer than two
11 hours heating.

12 Q It sounds like you think that if there was
13 a suspension in Liu, it probably would have been
14 more of the (E)-endoxifen material that was
15 suspended and more of the (Z)-endoxifen material
16 that was actually dissolved; is that right?

17 A I'm speculating a bit, but based on other
18 data, I think that would be correct.

19 Q Is it possible that the undissolved
20 (E)-endoxifen in Liu's Example 6 could have seeded
21 the crystallization steps in Liu such that Liu
22 produced more (E)-endoxifen than it would have had

1 the (E)-endoxifen all been dissolved in a solution
2 in Example 6?

3 A That's an interesting idea; however, I
4 think my results with the percentage of E and Z
5 correspond with Liu's. So it doesn't look like
6 that's the case.

7 Q Is it possible that that could have
8 happened, though?

9 A Well, there's no evidence to support that.

10 Q Is there any evidence -- withdrawn.

11 But it is a possibility?

12 A I think it's an unlikely possibility.

13 Q But a possibility, nonetheless?

14 A Yeah. I'm looking at -- my isomerization
15 experiment is on Page 34, and just -- just looking
16 at the ratios real quickly, and I'm seeing ratios
17 of 69 to 31, Z to E. 67 to 33. This corresponds
18 pretty closely to the ratio that Liu reports in
19 Paragraph 73.

20 So what I'm saying is that I don't -- I
21 don't see the slight differences between what Liu
22 did and what I did to be significant, and the end

1 result, there is no -- there is no difference.

2 Q You agree that by creating a solution
3 rather than a suspension in your recreation of
4 Example 6 you avoided the potential problem of
5 undissolved (E)-endoxifen seeding the
6 crystallization process?

7 MR. MAHON: Objection; form.

8 A I -- I disagree with the premise that
9 if -- if there was undissolved E at 85 degrees or
10 reflux, that that would be a bad thing. On the
11 contrary, if the E precipitated out, then that
12 leaves more Z in the mother liquor and gives more
13 E to use in an (E)-isomerization.

14 Q What is the mother liquor used for --
15 withdrawn.

16 You just mentioned the mother liquor.
17 What is that used for?

18 A That's -- the mother liquor is -- which is
19 the filtrate, is enriched in the (Z)-isomer.
20 There's a step that maybe I didn't mention, and
21 that involves removing a solvent, which is
22 isopropyl acetate, from the mother liquor. That

1 creates -- that gives you a material that would be
2 a solid, as it says at the bottom of Paragraph 73.

3 And then that can be used and
4 recrystallized from acetone to provide the even
5 more enriched, greater than 90 percent enriched
6 (Z)-endoxifen.

7 That's the whole purpose of the
8 isomerization.

9 Just so we're clear, the initial formation
10 gives approximately a 50/50 mix of Z and E. You
11 can throw away all of the (E)-isomer, or you can
12 isomerize it in isopropyl acetate followed by the
13 crystallized form acetone, and you can do that
14 cyclicly, repeatedly, and thereby not throw away
15 thousands of grams, in this case, of endoxifen.
16 That's the purpose.

17 MR. MILEA: Okay. Why don't we take a
18 break, and I will hopefully finish up soon after
19 that.

20 (A recess was taken.)

21 BY MR. MILEA:

22 Q Doctor, do you remember exactly how many

1 samples of material you sent to Dr. Miller?

2 A The samples that I sent to Dr. Miller are
3 recorded in my notebook when I say either Form 1
4 or not Form 1. I think there were four.

5 Q Okay. And so there were no other samples
6 other than the ones where you noted Form 1 or not
7 Form 1?

8 A I'm sure that's correct.

9 Q Do you recall if you sent him any samples
10 for which you didn't receive results?

11 A No. I always received results.

12 Q Okay. I'd like to switch gears a little
13 bit and look at the '391 patent, which is the
14 patent that's at issue in the PGR, and
15 specifically claim 16.

16 MR. MILEA: So if we're, please, able to
17 pull up PGR Exhibit 1034, which is the declaration
18 in the PGR.

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

21 BY MR. MILEA:

22 Q And, Doctor, I believe this is the

1 document which you had which is unsigned, so if
2 you're okay to just look at the exhibit that we
3 pull up on the screen rather than your unsigned
4 copy, let's do that.

5 Oh, we do have that up. Okay.

6 Doctor, do you see that on the screen?

7 A Yes.

8 Q Let's please turn to Paragraph 74.

9 We may have touched on this many hours
10 ago, but -- withdrawn.

11 Do you see claim 16 here up at the top,
12 right above Paragraph 74?

13 A I do.

14 Q And do you see claim 16 requires the
15 composition of claim 1 wherein the compound of
16 Formula 3 is stable in the composition for at
17 least 10 days at about 25 degrees Celsius?

18 A Yes.

19 Q And what that's saying is the
20 (Z)-endoxifen has to be stable in the claim
21 composition of claim 1, right?

22 MR. MAHON: Objection; form.

1 A That would be my understanding.

2 Q And that composition could include things
3 that are part of the formulation of the
4 composition, right?

5 A To be sure, we would have to look at the
6 wording of claim 1.

7 Q Sure, so let's do that. A good place to
8 find claim 1 would be in this same document on
9 Page 6, if you use the bottom middle, or Page 9 if
10 you're using the exhibit stamp.

11 A Okay. This is claim 1. Independent claim
12 1, composition comprising an endoxifen and an
13 enteric material wherein... (reading document to
14 self).

15 So I'll just point out that my
16 understanding of comprising means that it
17 contains, in this case, endoxifen and an enteric
18 material, and it may contain other things as well.
19 It's not limiting.

20 Okay. Endoxifen, comprised compound
21 Formula 3, which is shown there. The wiggly line
22 indicates -- it could be a mixture of E and Z.

1 Then it continues, or a pharmaceutically
2 acceptable salt thereof, and at least 90 percent
3 by weight, is (Z)-endoxifen.

4 Okay. I understand claim 1.

5 Q And so my question was: Does the
6 composition of claim 1 include other things that
7 are part of the formulation of the composition?

8 A That appears to be the case, that it would
9 include at least an enteric material.

10 I'm -- that's a legal question. I'm not
11 sure if the enteric material is optional, but my
12 understanding from this would be that it's
13 included in the claim 1.

14 Q Do you agree that the components of a
15 formulation can affect the stability of the active
16 ingredient in that formulation?

17 A Yes. In this specific case here, my
18 understanding is the purpose of the enteric
19 material is to decrease its susceptibility to
20 isomerization.

21 Q You performed stability testing for the
22 PGR, right?

1 A Yes.

2 Q And your stability testing was of the same
3 (Z)-endoxifen material that you synthesized based
4 on your recreation of Liu, right?

5 A That's correct. I believe it was the
6 100 percent Z sample.

7 Q So you tested -- withdrawn.

8 Because you tested the 100 percent Z
9 sample, you tested the stability of (Z)-endoxifen
10 on its own, right?

11 A That's correct. What would be -- what
12 would be called the bulk.

13 Q And so your test was not of (Z)-endoxifen
14 as part of any formulation, right?

15 A Correct.

16 Q And so fair to say that you didn't test
17 whether enteric material affected the stability of
18 the (Z)-endoxifen you tested?

19 A I did not test it with the enteric
20 material, but the enteric -- I'm sorry. The
21 enteric material would only increase the
22 stability.

1 So the stability testing that I did,
2 excluding any enteric material, would be more
3 sensitive as -- of stability. In other words, if
4 my material was stable, the material that included
5 the enteric coating or enteric material would be
6 even more stable, and almost completely stable
7 under these conditions.

8 Therefore, my reasoning would be that --
9 that Liu's procedure provides the material which
10 inherently is as stable or more stable than claim
11 1 of the -- which is this?

12 Q '391 patent.

13 A '391 patent, yes.

14 Q When you say enteric material, what are
15 you referring to?

16 A Well, it's a term of art in formulations.
17 Enteric refers to the gastrointestinal system and
18 the idea of enteric -- so-called enteric material
19 is to shield the drug from the acidic environment
20 of the stomach and allow it to pass into the more
21 neutral, higher pH environment of the intestines.

22 To put it simply, in this case, the idea

1 is to maintain the Z confirmation and prevent
2 it or greatly slow down its conversion into E.

3 Q The enteric material you're talking about,
4 are you referring only to a coating, or are you
5 referring to something else?

6 A You know, I think I'm getting outside of
7 my area of expertise, which from -- just the
8 expertise here would be pharmacology and
9 formulation, which -- and I -- it's outside the
10 scope of my report.

11 But I'll just tell you from my lay
12 knowledge that many tablets and capsules contain a
13 coating on the outside to protect them from
14 stomach acid.

15 Q I'm just trying to understand. When you
16 say enteric material, what are you including in
17 that?

18 A Again, that's purely outside the scope of
19 what I'm prepared to testify, but you can read
20 in -- probably in the disclosure for this
21 patent -- this is '391, did you say?

22 Q Yes.

1 A Yeah. I think you can read there or in
2 other POSITA patent applications, you can read
3 what they consider to be enteric materials.

4 I seem to recall them mentioning a whole
5 list of them. Most of them are polymers that are
6 well-known in the art. It is not something that's
7 unique here. They're very common when used in
8 drugs that have been on the market for decades.

9 Q In your -- several of your answers, you
10 used the words "enteric material," and I'm just
11 trying to understand what did you mean when you
12 said that?

13 A Understood. I think I already answered
14 that. It's -- in general terms, it's a material,
15 polymeric, that shields the active drug -- the
16 active pharmaceutical ingredient from degradation
17 by acid of the stomach.

18 Q And did you mean that it was a coating or
19 something else?

20 MR. MAHON: Objection; form.

21 A I guess I'm going to say that's outside my
22 area of expertise.

1 Q Okay. With the remaining time, I'd like
2 to talk about example seven. I was hoping we can
3 get through this before I actually run out of
4 time, that way everybody can go home or go away
5 from their desks.

6 But let's go back, please, to your IPR
7 declaration, which is Exhibit 1033. And I want to
8 look at Paragraph 61, please.

9 Do you see Paragraph 61 on the screen,
10 Doctor?

11 A Yes.

12 Q Do you see in Paragraph 61 you cite to Liu
13 Paragraph 26?

14 A Where do you see that?

15 Q It's six lines from the bottom.

16 A Yeah, okay. Let me familiarize myself
17 with this whole paragraph, and then I'll get back
18 to you.

19 Q Sure.

20 A Okay. This is how -- equivalent to the
21 experiments that we were discussing before the
22 break.

1 Q And by that, do you mean that Paragraph 26
2 of Liu is describing an alternate set of
3 procedures that one might follow?

4 A What I meant when I said that was that the
5 procedure that I use is what we were talking about
6 before the break. In terms of whether that is
7 consistent with Paragraph 26, that's quoted here
8 within the -- within the quotation marks. I'll
9 take a look at that again.

10 So my understanding of this is that,
11 again, Liu is giving a range of conditions, which
12 is broader than those used in the actual example,
13 but -- broader than but includes.

14 Q So it's possible to follow Paragraph 26 of
15 Liu but not follow example seven of Liu? Is that
16 fair?

17 A I think not fair. Here's what I do when I
18 look at patents, whether it's for a litigation or
19 for attempting to just follow them to provide a
20 customer with a material.

21 I would -- I would look to some extent at
22 the main part of the disclosure, and I would look

1 much more seriously at the actual examples. And
2 as all of us know, the purpose of the disclosure,
3 excluding the examples, is to teach the widest
4 variety of possibilities, and the purpose of the
5 examples is -- at least in the old days was to --
6 what was it called? -- show the -- what was the
7 word? There's a legal term. Best --

8 Q Best mode, probably?

9 A Yes, best mode. I would go with the best
10 mode.

11 Q Okay. I think you said that Paragraph 26
12 gives some broader parameters than example seven,
13 right?

14 A Yes.

15 Q And so it'd be possible to be within those
16 broader parameters of Example 26 and not be within
17 example seven's precise parameters, right?

18 A Right. And I would -- I would defer, if
19 that's the right word, to the actual examples.

20 Q Okay. Paragraph 26, the part that you
21 quote here, says that the solution can be held at
22 a second temperature for .5 hours to 10 days, or 2

1 to 72 hours, and in some cases, longer holding
2 times at the second temperature may be required.

3 Do you see that?

4 A Yes.

5 Q Does that anywhere say that someone
6 performing -- withdrawn.

7 Does that mention scratching the flask
8 anywhere?

9 A I don't see the word "scratching," but as
10 I've said several times before, the scratching is
11 a well-known technique taught in undergraduate
12 organic laboratory.

13 Q And does that Paragraph 26 that you quote
14 in Paragraph 61 of your declaration mention adding
15 any additional stirring time?

16 A You're asking me if the quotation says
17 anything about stirring?

18 Q Right. Does the part of Paragraph 26 of
19 Liu that you've selected to put in Paragraph 61 of
20 your declaration, does it mention anything about
21 stirring?

22 A I don't see "stirring."

1 Q Let's look at Paragraph 62 of your
2 declaration, please. And I want to also have
3 open, if possible, Paragraph 76 of Liu side by
4 side with this.

5 A I hate to interrupt your train of thought,
6 but I just want to repeat what I said hours ago,
7 that in recrystallization or crystallization, it
8 is generally my practice not to stir, but it's
9 other people's practice to stir, and I don't think
10 it makes a whole lot of difference. It's really
11 not a -- not a major point here.

12 Q Okay.

13 A In my -- in my opinion.

14 Q So on the left, we should have
15 Exhibit 1033 -- I'm seeing 1034. Thank you. And
16 on the right, we should have Paragraph 76 of Liu,
17 please.

18 MR. MILEA: I think you passed it.

19 Okay. Thank you.

20 Q Doctor, do you see on part of your screen
21 Paragraph 62 of your IPR declaration, and
22 hopefully on part of your screen Paragraph 76 of

1 Liu?

2 A Yes.

3 Q Paragraph 62 of your IPR declaration
4 says -- withdrawn.

5 Is Paragraph 62 of your IPR declaration
6 describing how you performed part of Liu Example
7 7?

8 A Let me make sure. Let me read
9 Paragraph 62 to myself.

10 Okay. I'm up to speed on Paragraph 62.

11 Q Is Paragraph 62 of your IPR declaration
12 describing part of how you performed Liu
13 Example 7?

14 And if it's helpful, you can look at
15 Paragraph 61, which may provide context.

16 A I don't think I have to look at 61 right
17 now.

18 Okay. I think I have an overview of the
19 two paragraphs of text.

20 Q Okay. And so is Paragraph 62 of your IPR
21 declaration describing how you performed part of
22 Example 7 of Liu?

1 A Yes.

2 Q Do you see in the first line you write,
3 This precipitate was then dissolved in refluxing
4 acetone, filtered while hot to remove a slight
5 precipitate, then cooled and stirred for 50 hours
6 at 4 degrees?

7 And I left out some of the amounts, but
8 was that right otherwise?

9 A Yes.

10 Q Do you agree that Example 7 of Liu does
11 not disclose filtering the precipitate while hot
12 to remove anything?

13 A Yeah. This is actually the opposite of
14 the suspension question that we went through
15 before the break. So in this case, Liu apparently
16 had a solution in acetone. I had a very small
17 amount of precipitate.

18 It would be standard practice -- it is
19 standard practice to remove a precipitate from the
20 hot solvent before you cool it down and initiate
21 precipitation.

22 Q Do you know what it is that you removed

1 from your mixture when you did that additional
2 filtering step?

3 A I did not characterize it.

4 Q Was it --

5 A I -- you know, actually, I could check on
6 that. I don't recall that I characterized it, but
7 if I did, it would have been a very small amount,
8 and the only thing I could have done, I think,
9 would be TLC.

10 But I can take a look in my notebook if
11 you're interested and see if I did run TLC on it.

12 Q All right. Let's do that. So I believe
13 it's going to be the second-to-last page of your
14 lab notebook, which is Page 35 of your lab
15 notebook. And if you're using the exhibit stamps,
16 it's Page 95.

17 A Yeah. There's -- there's no information
18 there that even gives that initial small, slight
19 precipitate. There's not even a notebook number
20 for it.

21 So I think I simply discarded it knowing
22 that (Z)-endoxifen is soluble in hot acetone.

1 Q So fair to say you removed something other
2 than (Z)-endoxifen from your material when
3 performing Example 7?

4 A I -- I think that's fair to say. And,
5 remember, it's a slight amount of precipitate.

6 Q Would it have been impurities that you
7 removed?

8 A Probably. That -- that would be my
9 intention.

10 Q Had you followed Liu as written, those
11 impurities would have been present in the final
12 product that you synthesized following Example 7;
13 is that fair?

14 A That's presumably -- that's presumably the
15 case. But an experienced chemist, even an
16 undergraduate, would -- would know that if there
17 is a precipitate in the hot solvent that it should
18 be removed to prevent exactly what you just said,
19 contamination with whatever that precipitate is.

20 Q Right. So by removing the precipitate
21 from your mixture, you likely or possibly
22 prevented contamination of your final product?

1 A Yeah. Again, as -- as an experienced
2 chemist would know to do.

3 Q Let's look at Page 95 of your lab
4 notebook, please. Page 36. I'm sorry.

5 This is -- at the top it says Example 7,
6 right?

7 A Yes.

8 Q Is this the Example 7 that you performed
9 using your material from your Example 6
10 experiments?

11 A The materials were obtained from Page 34,
12 and they are 15-34-2S and 4S. These are -- on
13 Page 34, isomerization was performed. The
14 filtrates are -- are 2S and 4S on Page 34. They
15 were combined and recrystallized from refluxing
16 acetone.

17 So that would be equivalent to example --
18 you know, I may have the wrong citation here. No,
19 that's okay.

20 Paragraph -- I'm sorry. Paragraph 30 --
21 Paragraph 76 describes recrystallization from
22 acetone. That's what we just looked at.

1 Q Okay. And so that would be Example 6?

2 A I think it's Example 7, Paragraph 76.

3 Q Okay. Oh, I'm sorry. I'm asking whether
4 the materials that you're using in that version of
5 Example 7 on Page 36 of your lab notebook, whether
6 that's taking the materials you made in Example 6
7 and recrystallizing them?

8 A I think that's correct.

9 Q Okay. Going back to our discussion about
10 the additional filtering of Example 7 that you
11 did, would the removal of the impurities by that
12 additional step have affected the final
13 polymorphic form of the material that you
14 generated?

15 A I'd say that's extremely unlikely for many
16 reasons.

17 Q Why?

18 A Well, for one thing, on -- if the material
19 is insoluble, it probably would not -- it would
20 probably remain as a solid, and such solids are
21 notoriously much slower to react with other solids
22 than a liquid would be.

1 The other reason is that I don't think it
2 would change the form because a great, great
3 majority of the material is the material that's
4 soluble in acetone and precipitates giving Form
5 2 -- Form 1. So I -- no, I don't think it would
6 change -- change the form at all.

7 Q And you said at the beginning -- or maybe
8 the last answer -- that it would be extremely
9 unlikely to change the form. Do you recall that?

10 A Yes.

11 Q Is it possible it could change the form?

12 A There certainly isn't any evidence from
13 the work that I've done or I cite in Liu that that
14 would be the case.

15 Q But it is possible that the impurities you
16 removed from Example 7 of Liu could have altered
17 the final polymorphic form that the material you
18 synthesized adopted?

19 A It's my opinion that that's not going to
20 happen.

21 Q So it's impossible in your view?

22 A It's also my opinion that nothing in

1 chemistry is impossible. There are always
2 surprises, but it's my opinion that it's extremely
3 unlikely.

4 Q Extremely unlikely does leave open the
5 possibility that it could happen, though, right?

6 A I'm -- I'm being a scientist and trying to
7 not say anything that can be proven to be correct,
8 but it is my strong opinion that it would not
9 change the form.

10 Q If we go back to your lab notebook,
11 please, there's a series of experiments reported
12 on Pages 33, 34, 35, and 36.

13 These are the experiments on which you
14 rely in your flowchart at Paragraph 71 of your
15 declaration, right?

16 A I think that's correct.

17 Q And you arrived at these experiments by
18 doing all of the prior experiments described in
19 the earlier pages of your lab notebook, right?

20 MR. MAHON: Objection; form.

21 A I wouldn't put it exactly that way. I
22 would say that I did some preliminary experiments,

1 for example, based on Song, which were totally --
2 I don't want to say useless, but weren't -- do not
3 lead to the expected or desired result based on
4 Song.

5 I did some other experiments where I
6 thought I could do simpler -- where I thought I
7 could simplify Liu, the procedure of Liu, and
8 those were not entirely successful.

9 And, frankly, I eventually decided that I
10 better follow Liu as closely as possible, and that
11 led to the desired results.

12 I would just add to that, you know, I
13 think from the questions that you were asking me
14 about, I think, Examples 6 and 7, that Liu
15 describes what he does, I think, pretty well, but
16 the first time you look at it, it is a little bit
17 confusing. I don't know if he could have done any
18 better. My notebook is probably even more
19 confusing.

20 But, you know, once you look at it and
21 digest it, comprehend what Liu is doing, and
22 follow the procedure, the results come out very

1 much as he has stated, which is that you get
2 greater than 90 percent (Z)-endoxifen and -- and,
3 not as he stated, but in my hands, you get Form 1.

4 Q Is it fair to say that preceding the
5 experiments on Pages 34 through -- excuse me,
6 Pages 33 through 36 of your lab notebook, you
7 performed different versions of Liu Example 2,
8 Example 3, Example 4, Example 5, and Example 6?

9 A I guess we'd have to go through them
10 individually, you know, which we already did at
11 the beginning.

12 There's Example 2, in which in my hands
13 the temperature had to be increased -- as I said,
14 I don't know if you want to go through all of this
15 again. There's Example 3, there's Example 4.

16 At the end of Example 4, before there was
17 any recrystallization, I got a, as I recall it, 52
18 to 48 percent mixture of E and -- what was it?
19 Yeah, E and Z. E to Z. I'm sorry. I'm going
20 back between E and Z and Z and E. Anyway, roughly
21 50/50, as did Liu.

22 And then the recrystallization

1 experiments, we've talked about. And, ultimately,
2 when I followed Liu's procedure closely, I got
3 Liu's results.

4 Does that answer the question?

5 Q My question was a little different. All I
6 was asking is you performed a number of
7 different -- I think what you said, preliminary
8 experiments, with various examples of Liu before
9 you arrived at the experiments that are on Pages
10 33 through 36, which are the experiments that you
11 relied on in your purification chart at
12 Paragraph 71 of your declaration; is that fair?

13 A Yeah. I guess I got thrown off because
14 you were talking about Examples 2, 3, and 4 as
15 well.

16 Q Okay. So is it fair to say that you
17 performed what you called preliminary experiments
18 with various different examples of Liu before you
19 arrived at the experiments that you describe on
20 Pages 33 through 36 of your lab notebook, which
21 are the experiments that you rely on in your
22 purification scheme at Paragraph 71 of your

1 declaration?

2 A I think that's reasonably fair.

3 MR. MILEA: All right. Thank you very
4 much, Doctor. I really appreciate the late
5 evening. I have no further questions at this
6 time.

7 THE WITNESS: Okay. No problem.

8 MR. MAHON: None from us.

9 (Off the record at 7:20 p.m.)

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2 I, Brooklyn E. Schweitzer, Registered
3 Professional Reporter and Notary Public in and for
4 the Commonwealth of Pennsylvania, do hereby
5 certify:

6 That RON BIHOVSKY, Ph.D., the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me before the commencement of such
9 deposition and that such deposition was taken
10 before me and is a true record of the testimony
11 given by such witness.

12 I further certify that the adverse party,
13 INTAS PHARMACEUTICALS LTD, was represented by
14 counsel at the deposition. I further certify that
15 the deposition of RON BIHOVSKY, Ph.D., occurred
16 remotely on Tuesday, January 20th, 2026, at 10:02
17 a.m. to 7:20 p.m.

18 I further certify the inspection, reading
19 and signing of said deposition was not waived on
20 the record by agreement of all parties. I further
21 certify that I am not related to any of the
22 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.



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 Conducted on January 20, 2026

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