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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD,

Petitioner,

v.

ATOSSA THERAPEUTICS, INC.

Patent Owner.

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

DEPOSITION OF JASON McCONVILLE, PH.D.

APPEARING REMOTELY FROM ALBUQUERQUE, NEW MEXICO

FRIDAY, JANUARY 16, 2026

11:00 A.M.

Job No.: 614361

Pages 1 - 112

Reported by: Adrienne M. Mignano, RPR

1 Deposition of JASON McCONVILLE, PH.D., held
2 via Zoom videoconferencing, pursuant to Notice,
3 before Adrienne M. Mignano, a Registered
4 Professional Stenographic Reporter and Notary
5 Public.

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A P P E A R A N C E S

ON BEHALF OF PETITIONER:

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ALSO PRESENT:

Sedrick Lampkins - Remote Technician

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C O N T E N T S

EXAMINATION OF JASON McCONVILLE, Ph.D.	PAGE
By Mr. Milea	5

E X H I B I T S

(Attached to the transcript)

EXHIBIT	PAGE
Exhibit 2050 Article titled "USP and Dissolution--20 Years of Progress"	103

1 Whereupon,

2 JASON McCONVILLE, Ph.D.,

3 being first duly sworn or affirmed to testify to
4 the truth, the whole truth, and nothing but the
5 truth, was examined and testified as follows:

6 EXAMINATION BY COUNSEL FOR THE PATENT OWNER

7 BY MR. MILEA:

8 Q Good morning, Dr. McConville. Thank
9 you very much for being here.

10 A Good morning.

11 Q Please state your full name.

12 A Jason Thomas McConville.

13 Q What is your address?

14 A 12901 Cedarbrook Avenue, Northeast,
15 Albuquerque, New Mexico.

16 Q Where do you work?

17 A The University of New Mexico.

18 Q Have you been retained by Intas to
19 provide testimony in the IPR and PGR proceedings
20 that bring us together today?

21 A Yes.

22 Q Do you have any papers in the room

1 with you?

2 A No.

3 Q And you understand today's deposition
4 pertains to both the IPR and the PGR in which
5 you've offered opinions, right?

6 A Yes.

7 MR. MILEA: Let's go ahead and please
8 put up Exhibit 1032 to the IPR, which is
9 Dr. McConville's declaration, and also
10 Exhibit 1033 to the PGR, which is
11 Dr. McConville's declaration in that proceeding.

12 REMOTE TECH: Stand by. The exhibits
13 will be dropped shortly in the chat.

14 MR. MILEA: Thank you.

15 BY MR. MILEA:

16 Q Dr. McConville, I'll just wait for
17 the link so that you can open this up on your
18 own computer as well.

19 A Okay.

20 Q You should have both of the links.
21 If you can please open Exhibit 1032 in the IPR,
22 which is your IPR declaration, and turn to

1 page 49.

2 A One second. Okay, page 49 of my
3 declaration.

4 Q Yes, using the page numbers in the
5 bottom middle of the pages.

6 A Okay.

7 MR. MAHON: Mike, I'm sorry to
8 interrupt. One of the declarations appears to
9 be the Bihovsky declaration that was dropped in
10 the chat.

11 MR. MILEA: Oh, I see. So this
12 should be -- we should have Exhibit 1032 from
13 the IPR and Exhibit 1033 from the PGR, and I
14 think, Ben, you're seeing Exhibit 1033 from
15 the --

16 MR. MAHON: From the IPR.

17 MR. MILEA: -- the IPR. Okay.

18 REMOTE TECH: Stand by. Give me just
19 a moment.

20 MR. MILEA: Thank you, Ben, for
21 flagging that.

22 REMOTE TECH: I just want to confirm

1 that this is the correct one that's being
2 displayed.

3 MR. MILEA: Yes, that's right. Thank
4 you.

5 REMOTE TECH: Gotcha. I'll drop that
6 in the chat quickly.

7 BY MR. MILEA:

8 Q Dr. McConville, you should see
9 hopefully what is your declaration in the PGR in
10 the chat now. If you could please open that up
11 and let me know if that's the right document.

12 A Yes, it looks like I have both the
13 documents, one related to the -- one related to
14 the '151 and the other one the '391 patents.

15 Q The '151 is the patent in the IPR and
16 the '391 is the patent in the PGR, right?

17 A Correct.

18 Q If you can please look at
19 Exhibit 1032 in the IPR, which is your IPR
20 declaration, and turn to page 49 using the page
21 number in the bottom middle.

22 A I'm there, yes.

1 Q Is that your signature on that page?

2 A Yes.

3 Q Please now look at Exhibit 1033,
4 which is your PGR declaration, and turn to
5 page 77 using the page number in the bottom
6 middle, and let me know when you're there.

7 A I'm there.

8 Q Is that your signature on page 77?

9 A Yes.

10 Q Have you previously served as an
11 expert witness in any litigations or PTAB
12 proceedings?

13 A I have, yes.

14 Q About how many times have you done
15 that?

16 A I don't know, maybe over 20 times
17 altogether.

18 Q So I take it you've sat for a number
19 of depositions before?

20 A I have, yes.

21 Q Okay. So I'll just quickly go over
22 some ground rules just to make sure we're on the

1 same page about everything if that's okay. You
2 understand I'll be asking you a series of
3 questions today?

4 A Yes.

5 Q And your job is to do your best to
6 answer those questions accurately and
7 truthfully?

8 A Yes.

9 Q If you don't understand any of my
10 questions, will you please let me know and I can
11 try to clarify or rephrase? Is that okay?

12 A Yes, fine.

13 Q And if you don't do that, I'll assume
14 that you've understood my question. Is that
15 okay?

16 A Okay, yes.

17 Q And as I know that you know, since
18 you've done this a number of times, we have a
19 court reporter here transcribing everything, and
20 she needs a yes or no verbal answer, not just a
21 head nod or anything like that, okay?

22 A Understood, yes.

1 Q I will try to take a break every
2 hour, but if you do need a break, please just
3 let me know and I'd be happy to take one as long
4 as we're not in the middle of a question. Is
5 that all right?

6 A Yes.

7 Q Okay. If you'd please turn to
8 Exhibit 1032, which is your IPR declaration, and
9 look at paragraph 15, and let me know when
10 you're there.

11 A Okay, I'm there.

12 Q Paragraph 15 says that you're "a
13 named inventor on thirteen patents or patent
14 applications"; is that right?

15 A Yes, thereabouts. I may have added
16 another one since this one, and one or two
17 possibly.

18 Q Okay. Can you describe generally
19 what those patents and patent applications
20 relate to.

21 A Yes. Most of them relate to drug
22 delivery formulation inventions.

1 Q Do any of them relate to drug
2 delivery formulation inventions using an enteric
3 coating or enteric material?

4 A It is likely within some of the
5 patents that there are some teachings related to
6 enteric coatings. I cannot recall offhand.

7 Q Do you know who Dr. Bihovsky is?

8 A Not personally, no.

9 Q Do you understand he's one of the
10 petitioner's experts in the IPR and PGR
11 proceedings?

12 A Okay.

13 Q Have you ever spoken to Dr. Bihovsky?

14 A No.

15 Q In the same document you have open,
16 which is Exhibit 1032 in the PGR, can you please
17 turn to paragraph 67.

18 A I'm there.

19 Q Do you see in the first sentence of
20 paragraph 67 you mention Dr. Bihovsky and
21 Dr. Miller?

22 A Yes.

1 Q And then at the end of that sentence
2 you cite Dr. Bihovsky's declaration and
3 Dr. Miller's declaration?

4 A Yes.

5 Q Did you review Dr. Bihovsky's
6 declaration before you signed your declarations
7 in this case --

8 MR. MILEA: Withdrawn.

9 Q In the IPR proceeding and the PGR
10 proceeding, did you review Dr. Bihovsky's
11 declarations before you signed your declarations
12 in those proceedings?

13 A I think so. I can't remember
14 everything back then. You know, there's a few
15 documents, but I believe I had.

16 Q If you hadn't --

17 MR. MILEA: Withdrawn.

18 Q So you cite Dr. Bihovsky's
19 declaration in your PGR declaration, and you
20 think that you saw Dr. Bihovsky's declaration
21 before you signed your declaration?

22 A I'm a little confused. In the PGR or

1 the IPR?

2 Q Sorry, let's talk about the PGR right
3 now.

4 MR. MILEA: Withdrawn.

5 Q In the PGR, in your declaration,
6 Exhibit 1032, you cite Dr. Bihovsky's
7 declaration at paragraph 67, right?

8 A Yes.

9 Q And you think that you saw
10 Dr. Bihovsky's declaration before you signed
11 your PGR declaration?

12 A I -- I mean, if -- if -- this is
13 related to x-ray crystallography, you know, and
14 I'm relying on Dr. Bihovsky's analysis and this
15 citation obviously refers to that analysis and,
16 you know, I assume that, somewhere along the
17 line, I had at least seen that analysis and this
18 is what it's citing to.

19 Q Do you remember if --

20 MR. MILEA: Withdrawn.

21 Q So you saw Dr. Bihovsky's declaration
22 or some version of it in the PGR; is that fair?

1 A At least this discussion. I can't
2 recall exactly the specifics of the timing of
3 reviewing documents.

4 Q Did you ever get a copy of
5 Dr. Bihovsky's declaration?

6 A Again, it would be -- I haven't
7 looked through all my records. I can't recall
8 everything, obviously, but I assume I have seen
9 this argument and this analysis.

10 Q Do you happen to recall whether --
11 MR. MILEA: Withdrawn.

12 Q Was it possible that you just saw a
13 portion of Dr. Bihovsky's declaration?

14 A I can't recall. I recall discussing
15 with counsel about it. And I can't recall, you
16 know, all the documents that came to me in what
17 order and when.

18 Q What are the pharmacokinetics of a
19 drug generally? What does that describe?

20 A In very broad terms, pharmacokinetics
21 is related to the time the drug is in the body
22 for -- particularly with respect to blood

1 concentrations.

2 Q Are there multiple different aspects
3 or parameters to the pharmacokinetics of a
4 particular drug?

5 A Yes. So in particular of importance,
6 as I said, it's related to the length of time
7 the drug stays in the body. So one might look
8 at the time to maximum drug absorption, known as
9 the Tmax. That concentration of maximum
10 absorption then is the Cmax. And the extent of
11 which the drug is in the body, the time it's
12 absorbed and eliminated known as the Area Under
13 Curve.

14 Q And those are all -- just to make
15 sure we have the same vocabulary, would you call
16 those all pharmacokinetic parameters, or how
17 would you refer to those?

18 A I would, yes. I'd think that they
19 would be called pharmacokinetic parameters.

20 Q Okay. I'd like to talk about each of
21 those --

22 MR. MILEA: Withdrawn.

1 Q You said Tmax is a pharmacokinetic
2 parameter?

3 A Yes.

4 Q And Tmax means the time it takes for
5 a drug to get to its maximum concentration in
6 the body; is that right?

7 A Yes.

8 Q Can the way that a drug is formulated
9 affect its Tmax?

10 A Yes.

11 Q What types of formulation ingredients
12 might affect the Tmax of a drug?

13 A There's quite a lot. But in general,
14 let's take, for example, a tablet dosage form.
15 If we thought of a drug within a tablet, we can
16 make the tablet dissolve quicker. This might
17 shorten the Tmax, for example, because the drug
18 might be able to dissolve quicker in the gut and
19 then be absorbed quicker.

20 Components used in formulations
21 generally will have a knock-on effect for the
22 pharmacokinetic parameters. So we could retard

1 the release of a tablet, and that might extend
2 the Tmax for a drug.

3 So slowing down the presentation of
4 the drug to dissolve in the gut may extend the
5 Tmax. So we might use rate-controlling
6 polymers, for example, to do that, as opposed to
7 disintegrants that might shorten the Tmax by
8 providing more rapid disintegration of the
9 tablet.

10 Q What does the word "enteric" mean?

11 A Enteric literally is related to the
12 intestines. And an enteric coating is designed
13 to dissolve within the intestine.

14 Q As opposed to within the stomach?

15 A Yes.

16 Q Fair to say, then, that an enteric
17 coating changes the Tmax of a drug?

18 A That would have to be tested.

19 Q Is the intent of an enteric coating
20 to extend the time between when the --

21 MR. MILEA: Withdrawn.

22 Q An enteric coating, I think you said,

1 prevents a given drug from dissolving in the
2 stomach; is that fair?

3 A Not necessarily. An enteric coating
4 prevents drug release in the stomach, let's say.
5 So a tablet wouldn't -- if it was an immediate
6 release tablet, a tablet wouldn't disintegrate
7 in the stomach. It doesn't really dictate what
8 the drug does. It dictates where it's
9 presented.

10 Q And if a drug is not presented in the
11 stomach, it would be presented at some later
12 time in the intestines, for example?

13 A Right. So if a tablet has an enteric
14 coating on it that is designed not to dissolve
15 in stomach acid, then once that tablet has
16 emptied the stomach and the pH is increased and
17 that's favorable for dissolution of the enteric
18 coat, then the drug has an opportunity to be
19 presented into the liquid of the gut at the time
20 in the small intestine and then has an option to
21 dissolve. And at that point, it has an
22 opportunity to be absorbed.

1 Q And as between a drug with an enteric
2 coating, as you've just described, and the same
3 drug without the enteric coating, is it fair to
4 say that the Tmax of the drug with the enteric
5 coating would be greater because there's a
6 longer time until it begins to be presented in
7 the small intestine?

8 A That, I can't tell at this point.

9 Q Would the Tmax be different between
10 those two drugs?

11 A I don't know.

12 Q But it's fair to say that the
13 formulation --

14 MR. MILEA: Withdrawn.

15 Q But it is fair to say that it is
16 possible that adding an enteric coating to a
17 drug could affect its Tmax, right?

18 A It could, yes.

19 Q Does whether a drug is formulated as
20 a solution, suspension, tablet or capsule have
21 the potential to affect its Tmax?

22 A Possibly.

1 Q Is it fair to say, then, that the
2 Tmax of a drug isn't an inherent property of the
3 active ingredient but instead depends on how
4 it's formulated?

5 A I would say there's a combination of
6 both.

7 Q And part of that combination is the
8 formulation?

9 A Yes. Formulations can be adjusted to
10 affect the dissolution rate of a drug and when
11 it starts dissolving, for example, as we've
12 discussed.

13 Q And that could affect the Tmax of
14 that drug?

15 A It could.

16 Q You mentioned an enteric coating
17 earlier. Is that different than an enteric
18 material?

19 MR. MAHON: Objection. Form.

20 A Well, I mean, I guess we have an
21 example within my report, or my declaration,
22 describing an enteric capsule which is made out

1 of an enteric material. So that wouldn't be
2 coated in an enteric material. It wouldn't need
3 to be.

4 So I mean, I guess you can take the
5 powdered form of an enteric material prior to
6 coating or you can form that into different
7 functional materials, I suppose, such as
8 capsule. Or you could use the same material and
9 then coat a tablet or a capsule as well. But
10 the material is a starting point, I suppose.

11 Q And the enteric material, that also
12 has the potential, if included in the
13 formulation, to affect its T_{max} ; is that fair?

14 A Well, certainly it has the potential
15 to delay when the drug can start dissolving.

16 Q And that might affect the drug's
17 T_{max} ?

18 A Yes.

19 Q Let's talk about C_{max} now. What is
20 C_{max} ?

21 A The C_{max} would be the maximum
22 concentration that the drug is absorbed to in

1 the plasma or the blood.

2 Q Is that a pharmacokinetic parameter?

3 A Yes.

4 Q What types of formulation ingredients
5 can affect the Cmax of a drug?

6 A Could you repeat that question again.

7 Q What types of formulation ingredients
8 can affect the Cmax of a drug?

9 A Well, in this case we could include
10 ingredients that help the drug to dissolve more
11 rapidly, such as surfactants. And that could
12 increase the rate of drug absorption to a
13 maximum. So anything that can enhance drug
14 solubility could help increase the Cmax.

15 Q Can enteric material change the Cmax
16 of a drug --

17 MR. MILEA: Withdrawn.

18 Q If enteric material were included in
19 a drug formulation, might that change the Cmax
20 of that drug?

21 A You'd have to test that.

22 Q But it's possible that it could be

1 changed by enteric material?

2 A That's not usually what enteric
3 materials are designed to do so I can't really
4 comment on it. I haven't given it that much
5 thought.

6 Q And enteric material changes where in
7 the body a drug is presented and, thus, where
8 the drug is absorbed as compared to a drug
9 without an enteric material; is that fair?

10 A Can you repeat that.

11 Q Earlier you said that an enteric
12 material might affect where the drug is absorbed
13 in the body, for example, rather than in the
14 stomach, it would be absorbed in the intestine
15 if it had an enteric material in it; is that
16 right?

17 A Well, more or less the -- an enteric
18 coating, let's say, can affect where the drug
19 begins to dissolve possibly. I mean, it's all
20 dependent on the particular drug itself, of
21 course.

22 And I suppose, given that, you know,

1 there are different absorption characteristics
2 along the GI tract. So you know, ultimately,
3 that can have an effect on absorption.

4 Q Would that effect on absorption have
5 an effect on Cmax potentially?

6 A It could.

7 Q I think you said that part of that
8 would be dependent on the drug itself. What do
9 you mean by that?

10 A Drugs have different solubilities,
11 different pH values. So the solubility of a
12 drug can affect its pharmacokinetic parameters.

13 Q Would that affect how much of a given
14 drug is released in the intestines --

15 MR. MILEA: Withdrawn.

16 Q So might that create a difference
17 between two drugs as to how much of each drug is
18 released, for example, in the intestines?

19 A I mean, specifically, I think we -- I
20 was trying to talk about solubility. Where it's
21 released, it could be dependent on an enteric
22 coat, as we discussed. So, you know, where the

1 drug is released in the intestine could affect
2 its solubility too.

3 Q Would the active ingredient in the
4 drug also affect the extent to which it is
5 released in the intestines?

6 A What do you mean? The concentration
7 or --

8 Q Would --

9 MR. MILEA: Withdrawn.

10 Q So as between two different drugs,
11 both of which are enteric coated with the same
12 enteric coating but they have different active
13 ingredients, would the fact that the active
14 ingredients are different affect the extent to
15 which each drug is released in the intestines?

16 A Well, if we had identical dosage
17 forms, let's say, and two different drugs with
18 the exact same enteric coating on them -- is
19 that the hypothetical?

20 Q Yes.

21 A Okay. No, I wouldn't expect -- I
22 wouldn't anticipate any difference in release

1 of -- from the dosage form.

2 Q I want to go back to talking about
3 Cmax.

4 Does whether a drug is formulated as
5 a solution, suspension, tablet or capsule have
6 the potential to affect the Cmax of that drug?

7 A It's possible.

8 Q Fair to say, then, that the Cmax of a
9 drug is an inherent property of that drug but
10 actually depends on how the drug is formulated?

11 A It's a combination of both, as I
12 said.

13 Q And one part of that combination is
14 the formulation?

15 A Yes. Formulations can be adjusted to
16 affect the pharmacokinetic parameters.

17 Q Let's talk about half-life. What is
18 a half-life as it pertains to a drug?

19 A Well, if we know the Cmax of a drug,
20 we can measure that by taking blood samples from
21 a patient over time, or a volunteer, let's say,
22 depending on the clinical trial, the phase of

1 the clinical trial.

2 But if we have a Cmax, we obviously
3 have a maximum concentration. The half-life is
4 the time it takes for that maximum concentration
5 to exactly reduce by half.

6 Q Is half-life a pharmacokinetic
7 parameter?

8 A Yes.

9 Q Can the way that a drug is formulated
10 affect its half-life?

11 A Yes. I mean, yes and no. I mean, so
12 I would say that the time to get to a particular
13 half-life can be affected by formulation, but
14 the actual half-life from the Cmax would not be
15 affected, no. The half-life is an inherent
16 property of the drug and can't be changed by
17 formulation characteristics.

18 Q Might the half-life of a drug change
19 depending on where in the body it is being
20 absorbed and interacting with the body?

21 A No.

22 Q Let's talk about Area Under the

1 Curve. Is that commonly abbreviated as AUC?

2 A Yes.

3 Q What is AUC?

4 A In simple terms, you might call it
5 the extent of drug absorption or the extent of
6 time the drug is in the body to have a function.

7 Q Is it fair to think of it as the
8 total amount of drug that is absorbed into the
9 body after administration?

10 A You could think of it like that, but
11 it's obviously also related to the extent of
12 time the drug is in the body after absorption.
13 So it's a time at which the drug can have a
14 therapeutic effect and it's related to
15 concentration.

16 Q Is AUC sometimes given as zero to
17 infinity?

18 A Yes.

19 Q What does that mean?

20 A Well, obviously, you know, if a
21 patient takes a dosage form, we can measure
22 their blood concentrations for a period of time.

1 We would measure their blood concentrations up
2 to the Cmax, for example, but -- you know,
3 giving us the Tmax time.

4 And then there's the downslope, the
5 elimination phase of the drug from the body
6 where the rate of drug absorption into the body
7 is less than the rate of elimination. So we see
8 this downward slope on the elimination curve,
9 the Area Under Curve.

10 So the pharmacokinetic profile will
11 take this form of a peak, showing the Cmax and
12 then this elimination phase, which is, you know,
13 as I said, an inherent property of the drug
14 where we get our half-life from.

15 We can only measure to a certain
16 period of time. And typically, clinically, if
17 you give a dosage form, you may be able to take
18 blood samples from a patient up to 12 hours,
19 let's say.

20 And then we may be able to plot that
21 on a graph, and we would have Area Under Curve
22 zero to 12, indicating we've got a zero to

1 12-hour time point. We might even be able to
2 pull the patient in 24 hours after
3 administration and get a 24-hour time point.
4 And so we would have an Area Under Curve zero to
5 24 showing.

6 To get the infinity time point, we
7 need to know the elimination rate of the drug,
8 which we can determine from the slope. And then
9 we simply are able to mathematically calculate a
10 theoretical portion of this slope down to zero
11 drug in the body. And that's what we term as
12 Area Under Curve zero to infinity.

13 Q Can the way that a drug is formulated
14 affect its Area Under the Curve zero to
15 infinity?

16 A Yes, because we can effectively
17 change the C_{max} and the broadness of this Area
18 Under Curve by adjusting the type of dosage
19 form. So, yes, formulation can affect Area
20 Under Curve.

21 Q One aspect of the formulation that
22 can affect Area Under the Curve zero to infinity

1 would be whether there's an enteric material in
2 the formulation; is that fair?

3 A I mean, possibly, but I wouldn't --
4 enteric materials aren't generally used for that
5 purpose. I can't think that it would generally
6 have much of an effect, no. Is it theoretically
7 possible? You don't really choose enteric
8 coatings to affect the Area Under Curve.

9 Usually you choose to have either
10 a -- some kind of extended-release-type
11 formulation to push that Tmax higher, broadening
12 out the Area Under Curve. It's not really the
13 job of the enteric coat to do that.

14 Q But it is possible that the inclusion
15 of an enteric material in a formulation could
16 affect the Area Under Curve zero to infinity?

17 A I mean, only by specifically
18 targeting areas of the gastrointestinal tract.
19 I mean, the enteric coat is generally designed
20 to allow the drug to start dissolving past the
21 stomach. You know, that's typically the job.

22 So you know, comparing -- you would

1 have to add something else to the formulation to
2 extend the Area Under Curve and affect that. So
3 if you compare --

4 Q So -- I'm sorry.

5 A Sorry. No, I was just going to say,
6 if you're comparing the two tablets, as I said
7 earlier, an immediate-release tablet versus an
8 extended-release tablet, and they are both
9 enterically coated, yes, they will have
10 different Area Under Curves potentially.

11 But if you're comparing two different
12 drugs with immediate-release tablets and they're
13 both enterically coated, then they're both
14 designed to deliver past the stomach.

15 Q As between two drugs which are
16 identical but for enteric material included in
17 one drug, would you expect the Area Under the
18 Curve zero to infinity for those two drugs to be
19 different?

20 A You'd have to test it, but offhand --
21 so we've got, sorry, an uncoated and a coated
22 tablet, is that what you're saying? Maybe you

1 need to repeat that. That's all.

2 Q Sure. Happy to.

3 MR. MILEA: Withdrawn.

4 Q As between two drugs which are
5 identical, other than the fact that one drug
6 includes an enteric material and the other drug
7 does not, is it possible that the Area Under the
8 Curve zero to infinity between those two drugs
9 could be different due to the presence of the
10 enteric material in one of those drugs?

11 A And we're specifically talking about
12 an enteric coat, are we?

13 Q Well, any kind of enteric material.

14 A So an enteric capsule instead of an
15 enteric coat?

16 Q Well, let's start with enteric coat.

17 A Okay. So one has an enteric coat and
18 one does not have an enteric coat. I honestly
19 don't know. It would have to be tested.

20 I can't foresee that there would be
21 any difference, you know, since the site of
22 absorption for drugs is generally located past

1 the stomach anyway. And it just depends. If
2 the drug degrades in the stomach, then, yeah,
3 there's less to absorb.

4 Q So you can't rule out that there
5 would be a difference between the AUC zero to
6 infinity for those two drugs?

7 A I can't say without testing, really.
8 I mean, it's difficult to say. But the enteric
9 coat is just designed to deliver a payload so
10 the dissolution can start.

11 Q What is the steady state level of a
12 drug in general terms?

13 A Steady state is generally reached
14 after a period of multiple doses are given to an
15 individual, and then blood plasma levels reach a
16 state at which drug going in equals drug going
17 out, by weight.

18 Q Is steady state level a
19 pharmacokinetic parameter?

20 A Yes, it could be considered a
21 pharmacokinetic parameter. It comprises -- if
22 you are taking a tablet, it comprises several

1 different measurable areas.

2 So you can have a steady state
3 minimum, a steady state maximum akin to a Cmax.
4 And then you can have an average steady state
5 value because the drug will fluctuate up and
6 down an average as the dose is taken.

7 Q Can the way that a drug is formulated
8 affect its steady state level?

9 A For a given dose, no, I don't think
10 so. I mean, just what can be affected is the
11 time it takes to reach steady state,
12 potentially. Assuming the drug is absorbed.

13 Q Does whether a drug is formulated as
14 a solution, suspension, tablet or capsule have
15 the potential to affect its steady state level?

16 A I mean, depending on the drug
17 absorption, you can change the level of the
18 steady state, possibly. But let's assume that,
19 you know, we put a particular dose in a dosage
20 form, we're expecting it all to be absorbed.
21 Then no, the steady state wouldn't be affected.

22 Q But it is possible to change the

1 formulation such that the steady state is
2 affected?

3 A We're really talking about dose
4 administered. So you can change the steady
5 state level, you know, all three of those
6 parameters, the steady state minimum, average
7 and maximum, by adjusting the dose, which is the
8 same as looking at how much is absorbed, really.

9 So you can offset that, even, by
10 increasing the dose as less is absorbed. So you
11 can play around with the formulation to give you
12 a steady state level. But, ultimately, you
13 can't -- you know, the steady state is dependent
14 on the elimination rate of the drug, which is
15 inherent.

16 Q Well, let's talk about elimination
17 rate. What is that?

18 A It's the rate at which the body can
19 process the drug to eliminate it, I suppose.

20 Q Can the way a drug is formulated
21 affect its elimination rate?

22 A No.

1 Q What is an elimination rate constant?

2 A So if you recall, we were talking
3 about the Area Under Curve. And past the Cmax,
4 we see a decline in drug concentration over
5 time. That decline is an exponential decline.
6 It's the first order decline in drug
7 concentrations from blood plasma or whole blood
8 or whatever serum.

9 So it's measurable. We can take
10 samples and measure that rate of decline over
11 time. And that's where we get our half-life
12 from as well. If you recall, we can find the
13 time at which the drug is at half the maximum
14 concentration it was.

15 But that slope can be transformed
16 into a linear slope, if you like, by taking the
17 natural log of that elimination curve. And that
18 gives us a straight line, and we can use that
19 straight line to mathematically determine a
20 gradient of elimination. And the gradient of
21 the elimination is the elimination rate.

22 Q Can the elimination rate constant

1 change based on how a drug is formulated?

2 A No.

3 Q Let's please look at IPR
4 Exhibit 1027.

5 MR. MILEA: And if you could please
6 drop that in the chat also.

7 REMOTE TECH: Stand by.

8 Q Dr. McConville, please let me know
9 when you've got access to Exhibit 1027.

10 A Okay, I have it.

11 Q What is IPR Exhibit 1027?

12 A It's a textbook -- or a reference to
13 a textbook known as Shargel and Yu. And it's
14 Applied Biopharmaceutics and Pharmacokinetics,
15 and this is the Seventh Edition.

16 Q Is this a document you cite in your
17 IPR declaration?

18 A Yes.

19 Q Is it a document that you use outside
20 of this case in your work formulating drugs?

21 A Yes. So I've used it. I'm not sure
22 what edition we're on now, but yes.

1 Q Fair to say it's a reliable document?

2 A Yes.

3 Q Please turn to page 36 of
4 Exhibit 1027, and that's using the page numbers
5 in the top left. And if you'd like instead to
6 use the stamped page numbers, it's page 47 in
7 the bottom right.

8 Let me know when you're there,
9 please, Doctor.

10 A Okay, I'm there.

11 Q Do you see on the right-hand column
12 of Exhibit 1027, page 47, there's a paragraph --

13 A Sorry, page 47. Sorry, apologies.

14 Q Using -- I'm sorry, using the numbers
15 in the bottom right. If it's easier, I'll just
16 refer to the --

17 A Oh, yeah. I'm there, I'm there.

18 Q -- number on the exhibit stamp.

19 A No, I'm there. It's 47 of 89. I'm
20 there.

21 Q Yes, yes. Do you see on page 47 of
22 IPR Exhibit 1027 there is a paragraph in the

1 right-hand column that begins with "The below
2 table"?

3 A Yes.

4 Q And that sentence -- the first
5 sentence of that paragraph says that, "The below
6 table shows pharmacokinetic data obtained from a
7 study conducted in rabbits following
8 administration of various formulations of rectal
9 suppositories containing aspirin."

10 A Okay.

11 Q And is the table that that sentence
12 refers to the table that we see at the bottom of
13 page 47?

14 A I believe so, yes.

15 Q Are the column headings Fs2, Fs4,
16 Fs9, Fs11 and Fas9 referring to different
17 formulations?

18 A Yes, I think so.

19 Q To be clear, those are different
20 formulations of the same drug, which is aspirin,
21 600 milligrams, according to this exhibit?

22 A It looks like it.

1 Q Do you see the third row of that
2 table says "Elimination rate constant"?

3 A Yes.

4 Q Do you agree that the elimination
5 rate constant is changing with each formulation?

6 A I mean, the elimination rate constant
7 for a drug is an inherent property, so any
8 change that you're thinking you can see here is
9 just fluctuation in the data for that drug.
10 It's not, you know, affected by the formulation,
11 if that's what you're suggesting.

12 Q Well, I'm just asking you if the
13 elimination rate constant for each formulation
14 in this table is different.

15 A Yeah, there might be little
16 differences.

17 Q Is it possible that impurities in a
18 given drug could affect its pharmacokinetics?

19 A I mean, not off -- I would say not
20 offhand. That's not something that usually is a
21 problem.

22 Q But it is possible?

1 A I don't know. In a very hypothetical
2 situation, if there was an active metabolite
3 affecting metabolism of a parent molecule,
4 something like that might do it. I mean, it's
5 very -- usually, no, there's not enough
6 impurities in anything to affect things like
7 that.

8 Q But there could be a situation in
9 which there are enough impurities to affect the
10 pharmacokinetics of a drug?

11 A I wouldn't -- it's not something that
12 one thinks about.

13 Q Let's please turn to PGR
14 Exhibit 1011. That's Ahmad 2010. And Ahmad is
15 A-H-M-A-D.

16 A Okay, I've got it. Yeah.

17 Q Okay, great. Thanks.
18 Do you recognize Exhibit 1011?

19 A Yes.

20 Q What is it?

21 A It's a paper by Ahmad related to
22 delivery of endoxifen.

1 Q Is this something you cite in your
2 PGR and IPR declaration?

3 MR. MILEA: Withdrawn.

4 Q Is this something you cite in your
5 PGR declaration?

6 A Yes.

7 Q Using the stamps in the bottom
8 right-hand corner of each page, can you please
9 turn to page 3 of Exhibit 20 -- excuse me,
10 Exhibit 1011.

11 A Okay. I'm there.

12 Q In the bottom right corner there's a
13 section entitled, "Methods," and there is a
14 subsection or paragraph that starts with
15 "Endoxifen synthesis."

16 A Okay.

17 Q The second sentence of that paragraph
18 says, in part, "Endoxifen citrate was prepared
19 as an enteric-coated tablet."

20 Do you see that?

21 A Yes.

22 Q Does Ahmad 2010 provide any other

1 information about how the endoxifen citrate was
2 formulated?

3 A I can't see any specifics other than
4 the enteric protein.

5 Q Is it possible that the endoxifen
6 citrate administered in Ahmad 2010 included
7 other formulation ingredients that could have
8 affected the pharmacokinetic parameters observed
9 in Ahmad 2010?

10 A Can you repeat that, please.

11 Q Is it possible that the endoxifen
12 citrate administered in Ahmad 2010 included
13 other formulation ingredients that could have
14 affected the pharmacokinetic parameters that
15 were observed in Ahmad 2010?

16 A I'm not sure I quite understand.
17 Obviously, there is a tablet formulation and we
18 see some data. Is it possible to use
19 ingredients to change pharmacokinetic
20 parameters? Yes, it's possible, but I assume,
21 from this paper, we have a standard formulation
22 and we see the data related to that. I don't

1 quite understand what you mean.

2 Q On page 2 of Ahmad 2010, there is a
3 table, Table 1 --

4 A Yes.

5 Q -- and it gives some various
6 pharmacokinetic parameters for different doses
7 of endoxifen, right?

8 A I see that.

9 Q Is it possible that the endoxifen
10 citrate administered in Ahmad 2010 included
11 formulation ingredients other than the enteric
12 coating that could have affected these observed
13 pharmacokinetic parameters?

14 A Well, I don't really want to comment
15 on that too much. If I recall correctly, some
16 of this data appears somewhere else too, and I
17 think we have more guidance on what the
18 formulation was. I don't think there is
19 anything special about these tablets.

20 Q But based on what's --

21 MR. MILEA: Withdrawn.

22 Q Based on the information in Ahmad

1 2010, you can't rule out that there were some
2 other formulation ingredients that could have
3 affected these observed pharmacokinetic
4 parameters?

5 A In what way? Affected how?

6 Q Well, for example, changed the Cmax
7 or the AUC zero to infinity.

8 A From what?

9 Q Just as two examples.

10 A But changed it from what?

11 Q As opposed to formulations with
12 different ingredients.

13 A I don't know what we're comparing
14 really. You know, if you'd be more specific
15 about the ingredients that you think might be in
16 Ahmad's formulations that are affecting the Cmax
17 and AUC, then maybe we'd have an idea. But I
18 can't see any obvious indication that there's
19 anything special about these tablets.

20 Q Can you rule out the possibility that
21 there were other formulation ingredients that
22 could have affected the Cmax and AUC zero to

1 infinity observed in Ahmad 2010?

2 A Well, normally, when you publish a
3 paper and there's something special about the
4 formulation, you highlight that. I can't see
5 that that's -- I mean, that's something to be
6 excited about when you publish a formulation,
7 that you've achieved something by the
8 formulation means. But I can't see -- one would
9 assume these are just standard tablets.

10 Q Let's take a look at PGR
11 Exhibit 1012, which is Ahmad 2012, please.

12 MR. MAHON: Mike, do you think it
13 might be a good time for a break after Ahmad
14 2012?

15 MR. MILEA: Yeah, it certainly would
16 be. I'm going to move on to another topic after
17 that.

18 MR. MAHON: Okay.

19 A One second. I'm just having an issue
20 scrolling down in my chat box. Hang on. One
21 sec.

22 Q Take your time.

1 A Okay, I've got it.

2 Q Is Ahmad 2010 a document that you
3 cited in your PGR declaration?

4 A Yes.

5 Q Is there any information about the
6 formulation of endoxifen that was administered
7 in Ahmad 2010? And feel free, it's only a
8 couple of pages. You can read the whole thing
9 if you like.

10 A Yeah, give me a moment. Let me just
11 see if I can see anything related to
12 formulation.

13 Q Sure. Take your time.

14 A Yeah, I don't see anything
15 specifically that pulls out formulation here.
16 One would assume, this being 2012, it's a
17 follow-on from previous work.

18 Q But fair to say there's no disclosure
19 of whether, for example, an enteric material was
20 used in Ahmad 2012's endoxifen?

21 A Sorry. You said whether enteric coat
22 was used? Is that what you said?

1 Q I'll repeat my question.

2 MR. MILEA: Withdrawn.

3 Q Is it fair to say there is no
4 disclosure, one way or the other, as to whether
5 an enteric material was included in the
6 endoxifen administered in Ahmad 2012?

7 A It doesn't specifically call it out.
8 Let me see. Hang on one second here.

9 Well, yeah, there's nothing specific
10 in the paper about formulation.

11 Q And given that there's nothing
12 specific about formulation, it's possible that
13 there were also some other formulation
14 components used?

15 A Again, I'm struggling with that. I
16 don't -- I would look at this and assume there
17 is nothing special about these tablets. I'd
18 probably assume they're enterically coated as
19 well, following on from the previous work.

20 It doesn't -- this is -- let me see.
21 This is simply an abstract, I believe, for a
22 presentation, if I'm not mistaken. And, you

1 know, often there is more information on the
2 presentation itself. And this is simply an
3 abstract showing some results and you're often
4 very limited in these abstracts.

5 Q Just to be clear, this is a document
6 you selected, right?

7 A Well, it shows endoxifen and it shows
8 concentrations which are applicable to the PGR.
9 And as far as I can tell, there is nothing super
10 special about these tablets. I assume they're
11 the same tablets Ahmad has been using in
12 previous work as well.

13 Q You cited this document in your PGR
14 declaration, right?

15 A Yes.

16 Q And you said it's just an abstract
17 and it doesn't really provide all of the
18 information that you might want to see; is that
19 fair?

20 A It provides the important information
21 related to the pharmacokinetic parameters.

22 Q Is the formulation of a drug --

1 MR. MILEA: Withdrawn.

2 Q Earlier we discussed how the
3 formulation of a drug can change pharmacokinetic
4 parameters, right?

5 MR. MAHON: Objection to form.

6 A Well, yeah, I mean, one can adjust
7 formulations to affect outcomes for the dosage
8 form in the body, yes.

9 Q And Ahmad 2012 doesn't say, one way
10 or the other, how it adjusted formulation
11 parameters that might affect the observed
12 pharmacokinetic parameters in Ahmad 2012, right?

13 MR. MAHON: Objection. Form.

14 A The presentation is generally showing
15 us different doses of endoxifen and the
16 pharmacokinetic parameters associated with that.
17 But that's pretty much the extent of information
18 related to the formulations.

19 Q It's fair to say, then, that missing
20 from Ahmad 2012 is any information about
21 formulation ingredients that might have affected
22 the pharmacokinetic results reported in Ahmad

1 2012?

2 A There's no specifics related to the
3 formulation ingredients, that's correct.

4 Q And that information --

5 MR. MILEA: Withdrawn.

6 Q And the specifics related to the
7 formulation ingredients might include
8 formulation ingredients that affect the
9 pharmacokinetic parameters reported in Ahmad
10 2012?

11 A Well, whatever the formulation is, it
12 provides these pharmacokinetic parameters.

13 Q And you can't rule out the
14 possibility that the formulation used in Ahmad
15 2012 is different than the formulation used in
16 Ahmad 2010?

17 A I mean, I would be surprised if it
18 was, but I can't see any specifics saying it's
19 different or not, either way.

20 Q So you can't rule out that it's
21 different?

22 A I think it's one of those things

1 that, you know, we have an endoxifen formulation
2 that's giving us this information,
3 pharmacokinetic information. And, you know, I
4 just -- I can't -- I don't know for certain what
5 Ahmad did. But I don't think there's anything
6 exciting about the formulation itself.

7 MR. MILEA: Let's take a break, if
8 that's okay with you, Dr. McConville.

9 THE WITNESS: Yes, sure.

10 (A recess was taken.)

11 BY MR. MILEA:

12 Q If you can please look at your IPR
13 declaration, Dr. McConville, which should be
14 Exhibit 1032 in the IPR.

15 A Yes.

16 Q And if you'd like, I want to talk
17 about claim 6 of the '151 patent. Claim 6 is on
18 page 9 of your declaration. It's the middle
19 bottom number. And if you use the stamp on the
20 right, it's page 12.

21 A Okay.

22 Q Claim 6 is "The composition of

1 claim 1, wherein greater than 90 percent by
2 weight of the (Z)-isomer in the composition is
3 crystalline Form I."

4 Do you see that?

5 A Yes.

6 Q Let's look at paragraph 28 through 31
7 of your IPR declaration, please.

8 A Okay.

9 Q In these paragraphs, 28 through 31,
10 is it fair to say you're describing Liu?

11 A Yes, that's correct. That is my
12 understanding, yes.

13 Q And is it fair to say you're -- here,
14 you're trying to convey what the benefits of Liu
15 are?

16 A To some extent, and Liu is teaching a
17 method of manufacture.

18 Q Is one of the benefits of Liu that
19 you talk about here described at the end of
20 paragraph 31, where it says, "Liu's procedure
21 'avoids the use of chromatography in the
22 separation of the Z- and E-isomers and enables

1 facile scale-up operations in multi-kilogram
2 quantities' "?

3 A Right. It's my understanding that
4 that's preferable from a manufacturing point of
5 view cost-wise, potentially.

6 Q So that's one of the beneficial
7 disclosures of Liu that you rely on?

8 A Yes.

9 Q And I think you said one of the
10 benefits of avoiding using chromatography is
11 cost. Are there any others?

12 A It's not really -- the manufacture of
13 chemical entities and their separation is not
14 necessarily my area of expertise. I know that
15 chromatography can be costly and time consuming.
16 So, you know, that's a go-to for me.

17 Q And so where possible, it's
18 preferable to avoid using chromatography. Is
19 that fair?

20 A I'm sure there are places, you know,
21 situations where it's unavoidable, but yet I
22 would imagine any cost-saving measure and

1 time-saving measure is preferable in any
2 situation given the scaleup.

3 Q Let's look at paragraph 32 of your
4 IPR declaration, which is just on the next page,
5 page 17 of 91. Are you there, Dr. McConville?

6 A Yes, yes.

7 Q Okay. And is paragraph 32 discussing
8 the disclosures of the Fauq reference, F-A-U-Q?

9 A Yes.

10 Q You say in the -- I guess it's the
11 third sentence --

12 MR. MILEA: Withdrawn.

13 Q You say in the -- I guess it's the
14 third sentence of paragraph 32 that "Fauq
15 discloses using high performance liquid
16 chromatography to separate the Z- and E-isomers
17 of endoxifen that are discussed in Fauq"; is
18 that right?

19 A Yes.

20 Q And then, later in that paragraph, in
21 the second to last sentence, if you count the
22 citation sentence, you say that again --

1 MR. MILEA: Well, withdrawn.

2 Q It's actually in the middle of that
3 paragraph. You go on to talk about another
4 portion of Fauq and say that the Z- and
5 E-isomers were re-subjected to HPLC separation.

6 Do you see that?

7 A Yes.

8 Q Is HPLC separation --
9 high-performance liquid chromatography
10 separation?

11 A Yes.

12 Q Fair to say then that both methods of
13 Fauq that you're describing here in paragraph 32
14 rely on chromatography to separate the Z and the
15 E endoxifen isomers?

16 A Yeah, as best I recall.

17 Q Is it also fair to say that Fauq's
18 use of chromatography in all of its procedures
19 is contrary to the benefits of Liu that you
20 tout, which are -- one of them being that Liu
21 avoids the use of chromatography?

22 A I mean, they're different.

1 Q On the one hand -- I'm sorry, go
2 ahead.

3 A Yeah, I would imagine that the Liu
4 method would be cheaper. I -- you know, as I
5 say, this is not necessarily scaleup.
6 Manufacturing is not completely my area of
7 expertise. I would imagine it would be better
8 not to use HPLC if you could.

9 Fauq says you can use it, but I would
10 imagine there's benefits to not using it if you
11 can scaleup.

12 Q Let's please turn to paragraph 67 of
13 your IPR declaration.

14 That's page 30 of 91 using the stamp
15 on the bottom right.

16 A Yes.

17 Q And at the end of that paragraph you
18 say in the last sentence, "Although Liu provides
19 sufficient knowledge to a POSA to do so" -- and
20 "doing so" is referring to purifying the
21 endoxifen; is that right?

22 A Yeah, with a reasonable expectation

1 of success.

2 Q Okay. And the sentence goes on to
3 say, "a POSA would have also been able to draw
4 on teachings in the art available before the
5 time of the invention, such as, for example,
6 Fauq and Milroy to arrive at the claimed
7 invention."

8 Does it say that, with the -- I
9 omitted the exhibit numbers, but did I otherwise
10 read that correctly?

11 A Yes.

12 Q And so a POSA looking at Liu and
13 looking at Fauq would see that Liu says you
14 should avoid chromatography and -- right?

15 A Well, I mean, there's a couple of
16 methods given. And a POSA does have a choice
17 then as, you know, what they -- what they could
18 follow in terms of manufacture. And it possibly
19 is bigger in terms of scaleup than just a single
20 person of ordinary skill could foresee, but they
21 can certainly draw on those teachings and see
22 that there's several different ways to

1 manufacture (Z)-endoxifen.

2 Q And one of those ways would have been
3 to, contrary to Liu's teachings, look at what
4 Fauq says about chromatography; is that fair?

5 MR. MAHON: Objection to form.

6 A Well, I mean, there's choices to be
7 made. I've said it's not really my area of
8 expertise, this scaleup, and I assume that using
9 chromatography is more expensive, but maybe
10 there's benefits to it that I'm -- that go
11 beyond the cost, I don't know. But there is a
12 choice to be made. There's a couple of options
13 that were in the prior art for manufacture, so I
14 can't see why having more than one source of
15 information is problematic, really.

16 Q You also in paragraph 67 mention the
17 Milroy reference, which is Exhibit 1022. Do you
18 mention or discuss Milroy anywhere else in your
19 declaration?

20 A I can't recall. I can't recall the
21 reference now either. But if that's the only
22 place, then obviously it relates to manufacture

1 purification. But I can't recall citing it
2 anywhere else because, you know, those are the
3 things that are dealt with in different areas.

4 Q So other than this passing mention of
5 Milroy in your declaration, fair to say you
6 don't discuss it at all?

7 A It's not something that sticks in my
8 memory.

9 Q Do you know whether Milroy discloses
10 the use of chromatography to separate (Z)- and
11 (E)-endoxifen?

12 A I can't recall. I mean, if you want
13 to show me the exhibit, that would be helpful.
14 Obviously, it is related to manufacture
15 purification, and it's not -- I've not described
16 it in detail there, so I can't really comment on
17 it too much.

18 Q If Milroy did disclose using
19 chromatography to separate (Z)- and
20 (E)-endoxifen, is it fair to say that that would
21 be contrary to Liu's teaching to avoid using
22 chromatography to separate (Z)- and

1 (E)-endoxifen?

2 MR. MAHON: Objection to form.

3 A I mean, I don't know whether contrary
4 is a very helpful term, really. It's just
5 another option. That's the way I see it. But,
6 you know, Liu has got an invention and describes
7 a way that it could be cheaper, as far as I can
8 see, and that's beneficial, but there may be
9 other benefits that I can't think of as I sit
10 here today. And, as I said, it is not totally
11 my area.

12 Q Fair to say at least, then, that
13 using chromatography as disclosed by Fauq or
14 Milroy would obviate one of the benefits of Liu
15 that you describe in your declaration?

16 A I think a person of ordinary skill
17 in, you know, a manufacturing entity would look
18 at various pros and cons. As I said, I think
19 Liu is potentially cheaper on paper, but what do
20 I know? I've never scaled anything up. So I
21 can't say yes or no to your question, really.

22 Q Okay, we can move on. I want to talk

1 next about claim 1 of the '391 patent. So if
2 you are able to get your PGR declaration, which
3 is Exhibit 1033 in the PGR, please.

4 A Yes.

5 Q Claim 1 is -- it starts on page 8 --
6 or page 13 of 121 if you're looking at the
7 stamp, and it goes on to the next page of
8 Exhibit 1033 of your declaration.

9 Do you see that?

10 A Yes.

11 Q I'd like to look at the preamble of
12 claim 1. It recites, "A composition comprising
13 an endoxifen and an enteric material, wherein."

14 Do you see that?

15 A Yes.

16 Q Is it your understanding that the
17 composition that is claimed and recited in the
18 preamble of claim 1 of '391 includes at least
19 endoxifen and an enteric material?

20 A Yes.

21 Q Are you familiar with the concept of
22 a dependent claim in a patent?

1 A Yes.

2 Q What is a dependent claim?

3 A Well, it depends on -- it has to
4 include the elements of the claim it is
5 dependent on.

6 Q When a dependent claim that depends
7 from claim 1 refers back to claim 1 and uses the
8 words "the composition," that dependent claim is
9 referring back to the endoxifen/enteric material
10 composition in the preamble of claim 1, right?

11 MR. MAHON: Objection. Form.

12 A Right. But as I understand, as it
13 says here, "endoxifen and an enteric material."

14 Q I think your counsel may have been
15 speaking at the same time. Did you say "right"
16 when you were answering my question?

17 A I was acknowledging that -- the
18 preamble of claim 1 where the composition
19 comprises endoxifen and an enteric material.

20 Q Just so the record is clear, let
21 me -- I'll re-ask my question.

22 MR. MILEA: Withdrawn.

1 Q When a dependent claim that depends
2 from claim 1 refers back to claim 1 and uses the
3 words "the composition," do you agree that that
4 dependent claim is referring back to the
5 endoxifen/enteric material composition in the
6 preamble of claim 1?

7 MR. MAHON: Objection. Form.

8 A I understand the -- whatever the
9 dependent claim has, it also refers back to this
10 preamble, which clearly states, "A composition
11 comprising an endoxifen and an enteric material"
12 as well. So the dependent claim has to
13 encompass those elements too.

14 Q Let's please look at claim 9 of the
15 '391 patent. And, Doctor, that's reproduced in
16 your declaration on page 15 of 121, using the
17 exhibit stamp.

18 A Yes, I see it, the top of page 10 in
19 the declaration.

20 Q Claim 9 says, "The composition of
21 claim 1, wherein the composition is formulated
22 as a suspension."

1 Do you see that?

2 A Yes.

3 Q Do you agree that "the composition,"
4 as used in claim 9, refers to both the endoxifen
5 and the enteric material of claim 1?

6 MR. MAHON: Objection. Form.

7 A My understanding is that the
8 dependent claim 9 is also encompassing the
9 independent claim 1, yes, which includes
10 endoxifen and the enteric material.

11 Q Let's look at paragraph 70, please,
12 of your PGR declaration.

13 A Okay. I'm there.

14 Q Is paragraph 70 your analysis of
15 claim 9 of the '391 patent?

16 A Yes.

17 Q Is this your entire analysis of
18 claim 9 in your declaration?

19 A Yeah, I believe.

20 Q Let's go back and look at claim 16,
21 please. And that's on page 10 of your
22 declaration, or page 15 of 121 if you're looking

1 at the exhibit stamp.

2 A Sorry, which claim again?

3 Q Claim 16.

4 A 16, okay.

5 Q Claim 16 depends on claim 1, right?

6 A Yes.

7 Q Claim 16 says, "The composition of
8 claim 1, wherein the compound of Formula (III)
9 is stable in the composition for at least
10 10 days at about 25 degrees Celsius," right?

11 A Yes.

12 Q Do you agree that claim 16 requires
13 the endoxifen to be stable in the composition
14 that also includes enteric material?

15 A So, yeah, since it's dependent on
16 claim 1, we have the endoxifen plus the enteric
17 material.

18 Q In your declaration do you discuss or
19 analyze any prior art or evidence regarding the
20 stability of endoxifen in a composition with
21 enteric material?

22 MR. MAHON: Objection to form.

1 A I can't recall whether I talk about
2 that stability aspect.

3 Q Can you please go to paragraph 119 of
4 your PGR declaration and let me know when you're
5 there.

6 A I'm there.

7 Q Do you, in these --

8 MR. MILEA: Well, withdrawn.

9 Q Is this your -- the entirety of your
10 analysis for claim 16 of the '391 patent in
11 paragraphs --

12 MR. MILEA: Withdrawn.

13 Q Are paragraphs 119 and 120 the
14 entirety of your analysis for claim 16 of the
15 '391 patent?

16 A So, obviously, now I recall
17 discussing stability, but yes, this is where I
18 give an overview of what I think relates to the
19 term "stable" as it pertains to claim 16, yes.

20 Q And these two paragraphs, 119 and
21 120, are the entirety of your analysis as to
22 claim 116?

1 A Yeah, I think that's pretty much it,
2 related to that stable aspect, yes.

3 Q Do you mention an enteric material
4 anywhere in these two paragraphs, 119 and 120?

5 A Well, I mean, in 120 I describe these
6 coatings, for example.

7 Q You don't mention an enteric coating,
8 though, right? Is that fair?

9 A I broadly mention coatings and pH
10 optimization.

11 Q But you don't specify an enteric
12 coating or optimizing pH through the use of an
13 enteric coating; is that fair?

14 A Well, I mean, I broadly mention
15 coatings and pH optimization, which covers that,
16 of course, but I don't call out enteric coatings
17 on their own.

18 Q Is it possible that the inclusion of
19 an enteric material in a composition could
20 affect the stability of the drug in that
21 composition?

22 A In what way?

1 Q In any way.

2 A I probably have to give that some
3 more thought because, obviously, we'd have to
4 think about the API itself, right, I think more
5 thoroughly in terms of -- in terms of that.

6 Q If the API were endoxifen, is it
7 possible that the inclusion of an enteric
8 material in the composition with the endoxifen
9 could affect the stability of the endoxifen?

10 MR. MAHON: Objection to form.

11 A Do you mean negatively affect the
12 stability?

13 Q Well, in any way could it affect the
14 stability?

15 A Well, applying coatings in general
16 are usually good for stability.

17 Q But it's possible it could have a
18 negative effect on stability?

19 A Well, I don't think so from what
20 we've seen so far. But, again, it's something I
21 would have to think about more thoroughly. I've
22 not really devoted a lot of time to thinking

1 about that.

2 Q So would you need some testing to
3 answer that question?

4 A It's standard to do stability testing
5 on formulations, yeah.

6 Q And so doing some testing would allow
7 you to answer the question of whether including
8 an enteric material in a composition with
9 endoxifen would affect the stability of the
10 endoxifen in that composition?

11 A I think it is standard practice to
12 look at stability profiles of drug compositions
13 to make sure that the patient gets the correct
14 dose in the end.

15 Q Without that testing, you can't
16 answer one way or the other whether the
17 stability of the endoxifen would be affected by
18 the inclusion of an enteric material in a
19 composition with the endoxifen; is that fair?

20 MR. MAHON: Objection. Form.

21 A I think it's routine testing for
22 stability, and as I mention in paragraph 120

1 there, if there are any stability issues, there
2 is a plethora of different options for a person
3 of ordinary skill to correct any stability
4 problems. It's well-known in the art.

5 Q My question is a little different. I
6 understand that you think the testing is
7 routine, but I'm asking whether, without that
8 testing, can you answer the question of whether
9 including an enteric material in a composition
10 with endoxifen would affect negatively the
11 stability of the endoxifen in that composition.

12 A I think it's something I could
13 potentially think about -- you know, a person of
14 ordinary skill could think about, let's say, and
15 then do some testing as well. And I think that
16 given some research into the area and some
17 testing, that that provides a more clear picture
18 on stability and, you know, obviously, testing
19 is extremely useful. Yes, as a formulator, I
20 would always like to see testing for stability.

21 Q Can impurities in a composition with
22 an active ingredient affect the stability of

1 that active ingredient in the composition?

2 A Sure, it's possible. It depends on
3 the API and the impurity, I suppose.

4 Q Would you need testing to determine
5 that?

6 A I would say the same as before, that
7 one would always expect to test things prior to
8 producing a drug product for a patient.

9 Q And that's because it's possible that
10 impurities in the drug composition could
11 negatively affect the stability of the active
12 ingredient in that drug composition?

13 A I mean, just from a stability point
14 of view, in general, one would test these
15 things. If there are specific impurities that
16 affect stability, then, yes, those should be
17 tested for too.

18 Q In order to determine whether there
19 are specific impurities that affect stability,
20 would you need to perform testing?

21 A I think it's fair to say that if
22 there was such a situation, then testing is

1 useful and would be necessary, I think, as a
2 quality control measure.

3 Q Let's look at claims 27 through 29 of
4 the '391 patent, please.

5 A Okay. I think I'm in the right
6 place, page 16 of 121.

7 Q Yes. And -- excuse me.

8 MR. MILEA: Withdrawn.

9 Q Do you see claim 27 is "The
10 composition of claim 1, wherein the composition
11 comprises from 1 milligram to 20 milligram of
12 (Z)-endoxifen"?

13 A Yes.

14 Q And claim 28 is the same except it
15 claims 1 milligram to 4 milligram of
16 (Z)-endoxifen?

17 A Yes.

18 Q And claim 29, similarly, is the same
19 as claims 27 and 28 except for the fact that it
20 claims 8 milligrams of (Z)-endoxifen?

21 A Yes.

22 Q Do you agree that each of claims 27,

1 28 and 29 require that the claimed composition
2 itself include the claimed amount of endoxifen?

3 A Yes.

4 Q For example, if we're looking at
5 claim 29, that would require a single dosage
6 form containing 8 milligram of endoxifen and an
7 enteric material; is that right?

8 MR. MAHON: Objection. Form.

9 A I think there's necessarily
10 8 milligrams of endoxifen, yes, plus whatever we
11 need from claim 1.

12 Q Would two 4-milligram --

13 MR. MILEA: Withdrawn.

14 Q Would two separate 4-milligram
15 tablets, each comprising endoxifen and an
16 enteric material, qualify as something that
17 would satisfy claim 29, which requires
18 8 milligram of endoxifen in a composition?

19 MR. MAHON: Objection. Form.

20 A Well, I -- I'm not sure.

21 Q Would two separate tablets, in your
22 view, be considered a composition?

1 A I would lean towards no, but,
2 obviously, there are ways to -- well, maybe it's
3 not obvious, but there's ways to encompass
4 different amounts of drug within a single entity
5 or composition.

6 Q If I took a 500-milligram tablet of
7 Tylenol in the morning and then at night I took
8 another 500-milligram tablet of Tylenol, would
9 you say that I took a composition of Tylenol
10 comprising 1,000 milligrams of Tylenol?

11 A No.

12 Q Let's look, please, at paragraph 78
13 of your PGR declaration.

14 Let me know when you're there,
15 please, Doctor.

16 A Okay, I'm there.

17 Q Is paragraph 78 your analysis for
18 claims --

19 MR. MILEA: Withdrawn.

20 Q Is paragraph 78 your analysis for
21 claims 26, 27 and 33 of the '391 patent?

22 A Yes, that's in that -- yeah, it

1 covers those claims, yes.

2 Q And in paragraph 78 you say that
3 "Ahmad discloses 1 to 10 milligrams per day of
4 endoxifen," and then you cite Ahmad. I think
5 you --

6 MR. MILEA: Withdrawn.

7 Q Do you see the first sentence of
8 paragraph 78 is "Ahmad discloses 1 to
9 10 milligrams per day of endoxifen"?

10 A Yes.

11 Q And then you cite Exhibit 1004.
12 Ahmad is Exhibit 1003, right?

13 A You know, I can't recall. There are
14 several Ahmad references.

15 Q Is the Ahmad you're referring to here
16 in paragraph 78 the Ahmad that is U.S. Patent
17 9,333,190? And if it helps, you can look at
18 page 14 of your declaration.

19 (Witness reviewing document.)

20 A Yeah, I don't know, maybe we can pull
21 up the Ahmad reference again to make sure we're
22 not --

1 Q Sure. So let's do that.

2 MR. MILEA: If we could please pull
3 up Exhibit 1003 in the PGR.

4 Q And I'm -- Doctor, I'm not trying to
5 trip you up on this. I just want to make sure
6 we're talking about the right exhibit, so I'm
7 happy to pull that up.

8 A Yeah, sure. I mean, if there is typo
9 there, I want to, you know, make sure we're
10 citing the right thing.

11 Q Yes.

12 REMOTE TECH: And, Counsel, you said
13 1003 in the PGR?

14 MR. MILEA: Yes, please.

15 REMOTE TECH: Stand by.

16 (Pause)

17 I'm sorry, give me just a moment. My
18 Adobe wants to freeze at the moment. I'm
19 closing it out and reopening.

20 MR. MILEA: That's fine. Take your
21 time.

22 (Pause)

1 REMOTE TECH: Counsel, if possible,
2 are we able to go off the record? I may have to
3 reboot.

4 MR. MILEA: That's fine, yes.

5 MR. MAHON: I know it's a little
6 early, but do you just want to take a
7 couple-minute break here?

8 MR. MILEA: Yeah, that's fine. And
9 then I think we can probably finish up in the
10 next session within -- I'd be surprised if it
11 took an hour.

12 MR. MAHON: So 1:15 Eastern, maybe
13 like 1:25 Eastern, 11 -- if I'm doing the math
14 right, 11:25 New Mexico time?

15 THE WITNESS: That is correct.

16 MR. MILEA: Okay, sounds good.

17 (A recess was taken.)

18 MR. MILEA: Before the break, we were
19 trying to mark Exhibit 1003 in the PGR. If we
20 could please do that and put it in the chat.

21 And then, Dr. McConville, let me know
22 when you have it.

1 And when I say mark the exhibit, I'm
2 referring to an exhibit that's already been
3 marked. I just mean display Exhibit 1003. So
4 I'm sorry if that's confusing.

5 BY MR. MILEA:

6 Q Have you got Exhibit 1003 in front of
7 you?

8 A Yeah, I just got it up.

9 Q Okay. And this is the document you
10 refer to as Ahmad in your declaration in the
11 PGR; is that right?

12 A It's -- yes, it's one of them.

13 Q And the others being Ahmad 2010 and
14 Ahmad 2012?

15 A Yeah.

16 Q Okay. And then do you happen to
17 still have your declaration in the PGR handy?

18 A Yes.

19 Q Do you see on page 14 the heading
20 "A," where you give the 9,333,190 patent --

21 A Yes.

22 Q -- number, and then you say "Ahmad"

1 in quotes?

2 A Yes.

3 Q Okay. Let's go back to paragraph 78
4 of your PGR declaration, please.

5 Have you got that, Doctor?

6 A Yes.

7 Q Okay. And so you say in
8 paragraph 78, "Ahmad discloses doses of 1 to 10
9 milligrams per day of endoxifen," and then you
10 cite Exhibit 1004, column 29, lines 20 through
11 31?

12 A Yes.

13 Q If you could please look at
14 Exhibit 1003, which is Ahmad, and just confirm
15 that that's what you meant to cite?

16 A Yes, I believe it is.

17 Q Okay. I just wanted to make sure we
18 were on the same page about that. So going back
19 to paragraph 78, is it possible that Ahmad's
20 doses of 1 to 10 milligrams per day endoxifen
21 were multiple doses as opposed to one single
22 dose of endoxifen?

1 A Well, when I look at the claims of
2 the '190 reference of the Ahmad, 1003, it talks
3 about a solid pharmaceutical composition. And
4 that 1 to 10 milligram per day stems from
5 example 15, I believe.

6 So it talks about a composition.

7 Q I'm sorry, what -- you're looking at
8 what claim of Ahmad?

9 A Well, there is only one claim.

10 Q Oh, okay. I see. So you're looking
11 claim 1 of Ahmad.

12 A Yes.

13 Q You don't refer to claim 1 in your --
14 in paragraph 78 of your declaration, right?

15 A Well, I mean, there's only -- there's
16 only the single claim, as I say, and in the
17 enablement, Ahmad describes this 1 to 10
18 milligram per day. You know, that could cover a
19 range of single doses. But I am not sure what
20 that takes, but in the claim, Ahmad describes a
21 composition.

22 Q And that claim is not referenced in

1 your analysis --

2 MR. MILEA: Withdrawn.

3 Q Ahmad's claim 1 is not referenced in
4 your analysis of -- in paragraph 78 of your PGR
5 declaration, right?

6 A Well, insomuch as, you know, I cite
7 the reference, obviously it includes the claim.
8 But I don't call it out as that because the
9 claim itself doesn't give the dose range. It
10 talks about purity of (Z)-endoxifen.

11 Q And that claim could be referring to
12 some other portion of Ahmad; is that right?

13 MR. MILEA: Withdrawn.

14 Q Claim 1 of Ahmad, which claims, in
15 part, "a solid pharmaceutical composition,"
16 there is no indication in that claim that it is
17 referring to the 1 to 10 milligram per day dose
18 range that you cite in your PGR declaration; is
19 that fair?

20 A The dose range is taught in the '190
21 reference.

22 Q The dose range of 1 to 10 milligrams

1 per day? Is that what you're referring to?

2 A Yes.

3 Q And is it possible that the dose
4 range of 1 to 10 milligrams per day is referring
5 to multiple doses totaling 1 to 10 milligrams
6 per day?

7 A Well, I would lean to say it is not
8 multiple doses just because example 15, where
9 the dose range comes from, talks about
10 extended-release formulations within there as --
11 it -- I can't say for sure, okay? I'll just --
12 I'll say -- I'll leave it at that. But it is a
13 dose range. It could be a single dose. And
14 since the claim talks about composition, you
15 know, that's where I lean.

16 Q But the portion of Ahmad that you
17 rely on in your PGR declaration at paragraph 78,
18 which is column 9, lines 20 through 31, that
19 doesn't say one way or the other whether that
20 1 milligram to 10 milligram per day range is
21 administered in a single dosage form or in
22 multiple dosage forms; is that fair?

1 A Correct. It doesn't specify
2 explicitly.

3 Q And it is possible that that 1 to
4 10 milligrams per day could be administered in
5 multiple doses over the course of a day totaling
6 1 to 10 milligrams per day?

7 A I wouldn't necessarily like to say I
8 agree with that. That's potentially, you know,
9 a clinical evaluation whether that's possible or
10 not.

11 Q So you don't have an opinion as to
12 the --

13 MR. MILEA: Withdrawn.

14 Q So you don't have an opinion as to
15 whether Ahmad's disclosure of 1 milligram to
16 10 milligrams per day endoxifen discloses a
17 single dose or multiple doses of endoxifen
18 totaling those amounts?

19 A I lean on it being a single dose just
20 because Ahmad's further work indicates single
21 oral dosage within that range, 1 to
22 10 milligrams as a single dose as well.

1 So although it doesn't explicitly say
2 and I can't say for certain, but based on the
3 claim where I'm talking about composition and
4 further word by Ahmad, you know, I lean to it
5 being a single dose.

6 Q Let's talk about claim 17 of the '391
7 patent, please. And if you would like to scroll
8 back up in your declaration, claim 17 is recited
9 on page 10, which is page 15 of 121, if you're
10 using the exhibit stamp.

11 A I'm there, yeah.

12 Q Claim 17 is "The composition of
13 claim 1, formulated such that the composition is
14 resistant to dissolution in an acidic
15 environment for at least 2 hours, as measured in
16 a dissolution test performed according to a
17 method of USP 711."

18 Do you see that?

19 A Yes.

20 Q What is USP 711?

21 A It's a chapter in the United States
22 Pharmacopeia that deals with dissolution

1 testing.

2 Q Is that a standards organization that
3 publishes that?

4 A Correct, yes, United States
5 Pharmacopeia.

6 Q How often are those standards
7 updated?

8 A The pharmacopeia itself, it varies on
9 the update from -- it can be anything from two
10 years to five years when there is revision
11 published. Often those revisions are related to
12 monographs. There are sometimes overhauls of
13 the testing. But this sort of dissolution
14 testing, for example, it's been around for
15 decades with little or no adjustment.

16 Q What is a monograph?

17 A A monograph generally relates to a
18 particular dosage form or drug product which is
19 new, and then that needs to be included within
20 the pharmacopeia. And then the pharmacopeia
21 will list specific test methods for quality
22 control and stability and things like that,

1 different suitable tests for the drug product
2 itself.

3 The monograph, just to add, may point
4 the reader in the direction of the testing
5 paragraphs, such as 711 -- testing chapters,
6 sorry, such as USP 711. So the monograph itself
7 will say, use dissolution test apparatus A in,
8 you know, USP Chapter 711.

9 Q But it is possible that a monograph
10 might have its own unique dissolution testing
11 procedures that are different than USP 711?

12 A So 711 is the general guidance.
13 There will be specific listing within the
14 monograph for the particular drug itself.

15 Q What is paracetamol?

16 A Known in the U.S. as acetaminophen.

17 Q Is that the active ingredient in
18 Tylenol?

19 A Yes.

20 Q Does Tylenol have its own monograph?

21 A I believe so.

22 Q Do you know whether the monograph for

1 Tylenol has dissolution testing procedures that
2 are different from those in USP 711?

3 A You mean does it have unique
4 dissolution? So -- so, yeah, I see what you
5 mean -- oh, sorry, I've just lost visual, but
6 it's back on. I don't know what happened.
7 Okay.

8 So Tylenol itself exists as an
9 immediate-release dosage form, and I believe the
10 sustained-release dosage forms as well. And
11 there is under the monograph a listing for
12 dissolution testing of a product, but like all
13 drug products, the active ingredient is
14 distinct. So, for example, acetaminophen can
15 exist as a powder and is not really under the
16 monograph for the USP.

17 So the powder itself is not a drug
18 product. A tablet or a capsule containing the
19 powder, the API, is a drug product.

20 Q So --

21 A In --

22 Q I'm sorry, go ahead.

1 A In pharmaceuticals, when we're doing --
2 investigating new formulations, for example, we
3 will use active ingredients from across the
4 board as model drugs in our testing. We're
5 really just testing the performance of a new
6 dosage form. It doesn't matter what the drug
7 product or the API powder is.

8 So I often use caffeine as a starting
9 material for looking at new drug product.
10 Sometimes I use acetaminophen. I use ibuprofen.
11 I use poorly soluble drugs as well, such as
12 theophylline and itraconazole as model test
13 drugs.

14 And suddenly acetaminophen is one of
15 those model test drugs which has been exposed to
16 almost every type of dissolution scenario you
17 can imagine.

18 Q Just for the court reporter, the last
19 two drugs that you mentioned, the last two
20 active ingredients, are you able to spell those,
21 please?

22 A For the poorly soluble drugs that I

1 mentioned in my examples, the theophylline and
2 the itraconazole?

3 Q Yes, please. Can you spell those.

4 A Yes, I'll have a go. So theophylline
5 is T-H-E-O-P-H-Y-L-L-I-N-E, I believe. And then
6 itraconazole is I-T-R-A-C-O-N-A-Z-O-L-E.

7 Q Thank you. And I just Googled those
8 while you were spelling them and that's right.
9 I just didn't want to attempt to spell them
10 myself because I didn't know where to start, but
11 thank you for that.

12 A Okay.

13 Q So going back to our discussion, is
14 it fair to say that you would follow --

15 MR. MILEA: Withdrawn.

16 Q When you do dissolution testing of
17 those types of drug substances, do you follow
18 the monographs for the approved drugs that those
19 drug substances are in?

20 A Not all the time. So for the new
21 types of formulations, for example, one will use
22 the USP for guidance. So particularly in this

1 example for an enteric-coated drug product,
2 there is sort of a standard dissolution test for
3 enteric drug products. And it requires putting
4 the drug product in an acidic media for a couple
5 of hours and then changing that media or at
6 least neutralizing that media to have a pH which
7 is elevated to mirror what might happen in the
8 small intestine, the pH change from the stomach
9 to the small intestine.

10 And that two hours' time in the
11 acidic media is supposed to reflect somewhat of
12 a time that a dosage form might be expected to
13 stay in the stomach before it is emptied intact,
14 so as a whole, without disintegrating.

15 And so that would be called, you
16 know, anecd- -- well not anecdotally -- we know
17 that as being an enteric dissolution test. It's
18 commonly used. And so we would use model drugs,
19 such as acetaminophen, to test our new drug
20 products because we can detect acetaminophen
21 very easily in the lab. And it would be a
22 starting point, and then we might move to the

1 particular API that we're really interested in
2 after using the model drug such as
3 acetaminophen. And what that would tell us is
4 how the drug product itself performs
5 irrespective of what drug is in it.

6 Q When you are using acetaminophen as
7 an example in your experiments, do you follow
8 the Tylenol monograph or something else when
9 you're performing dissolution testing?

10 A Well, since Tylenol is not really a
11 new drug product, it is likely I will use a
12 dissolution test method applicable to the type
13 of formulation I'm developing. So, for example,
14 if it is immediate-release formulation, well,
15 yes, it may well follow the type of Tylenol
16 dissolution monograph because what that will
17 also tell me is, you know, what detection method
18 to use as well.

19 And so Tylenol being generally an
20 immediate-release dosage form would give me
21 enough information to test for an
22 immediate-release drug product. But it is not

1 the fact that I'm using acetaminophen. I could
2 use any other drug in there too, caffeine even.
3 If I'm just looking at immediate-release, I
4 could use the Tylenol methodology, let's say.

5 But if I wanted to enteric coat the
6 Tylenol -- or the acetaminophen tablet, because
7 I'm looking at, you know, an enteric dissolution
8 process, it may not be exactly the same as what
9 is listed in the monograph, I'll just use a
10 standardized sort of enteric dissolution
11 process, but I could include Tylenol -- or,
12 sorry, acetaminophen as the powder in the drug
13 product and then just adapt the dissolution
14 method to show that it's performing this enteric
15 function.

16 Q And so it sounds like you would
17 probably use a custom-made dissolution testing
18 method when you're doing something like that?

19 A Well, a recognized dissolution test
20 method. So for sure it is very likely that one
21 of the monographs within the USP will have a
22 suitable dissolution test method, and the only

1 thing that might need to be adapted is the
2 detection method of the drug. But the
3 performance of the dosage form will follow a
4 prescribed test. It's just where it is in the
5 pharmacopeia.

6 So when we use a model drug, we use,
7 you know, a selected test which is designed to
8 evaluate the dosage form where we're developing.

9 Q Is it fair to say, when you're
10 testing an enteric material --

11 MR. MILEA: Withdrawn.

12 Q Is it fair to say, when you're
13 performing dissolution testing of an enteric
14 material, that you would have a wide variety of
15 different tests you could select from and adapt
16 in order to do the dissolution testing of that
17 material?

18 A Well, not necessarily. To test
19 whether an enteric material or a protein on a
20 tablet is working, you would use the prescribed
21 enteric dissolution test, which is a couple of
22 hours at low pH followed by an increase in pH,

1 to then see if the enteric coating dissolves and
2 releases the drug correctly. In the acidic part
3 of it, it shouldn't.

4 Q When you say, "the prescribed enteric
5 dissolution test," what are you referring to?

6 A Generally use the enteric dissolution
7 test.

8 Q Which is where -- where is that
9 written down?

10 A It can be found within the United
11 States Pharmacopeia. It can also be found under
12 the FDA guidance for enteric dissolution
13 testing, I believe.

14 Q Is it USP 711 or is it something
15 different, that you remember?

16 A USP 711 has the information to
17 perform that test, yes.

18 Q Do you know whether between --

19 MR. MILEA: Withdrawn.

20 Q Were you a formulation scientist in
21 2001?

22 A Yes.

1 Q Okay. Do you know whether, in 2001,
2 the USP 711 test was different than it was in
3 2017?

4 A I don't think so. I'd have to look
5 at it.

6 Q Let's look, please, at paragraph 136
7 of your PGR declaration. And this should be
8 Exhibit 1033 in the PGR. I'm seeing on the
9 screen right now Exhibit 1032 in the IPR.

10 A The -- sorry, which paragraph? 136,
11 you said?

12 Q Yes, 136 in the PGR declaration.

13 A Okay. I'm there.

14 Q Is paragraph 136 part of your
15 analysis of claim 17 of the '391 patent?

16 A Yes.

17 Q And in paragraph 136, you say, "Cole
18 does not explicitly disclose that the method
19 used" --

20 MR. MILEA: Withdrawn.

21 Q And in this paragraph you're talking
22 about the Cole reference; is that right?

1 A Yes.

2 Q And you're relying on Cole's
3 dissolution testing of paracetamol to show the
4 requirements of claim 17 of the '391 patent; is
5 that right?

6 A Yes, it is a pretty standard test.

7 Q And you say, "Cole does not disclose
8 explicitly that the method used was USP 711."
9 Do you see that?

10 A Okay, yes.

11 Q And you go on to say, "USP 711 is the
12 most common method for dissolution testing.
13 Therefore, a POSA would understand from Cole's
14 methodology that Cole was using USP 711."

15 Do you see that?

16 A I mean, it's very commonly used.
17 It's -- you know, the USP 711 has a variety of
18 dissolution test methods, but for enteric
19 coating this is really the method that everybody
20 thinks of first, and Cole as well would have
21 thought of this for sure.

22 Q Did Cole and his team --

1 MR. MILEA: Withdrawn.

2 Q Do you know when Cole was published?

3 A Oh, I can't recall.

4 Q If you'd like, let's go up to page 21
5 of your declaration, please, in the PGR.

6 A Okay.

7 Q And do you see there is a heading
8 there that talks about Cole and it gives the
9 date, 2002?

10 A Yes.

11 Q Does that refresh your memory that
12 Cole was published in 2002?

13 A That's what it says, so yeah.

14 Q So in 2002, did Cole and team have
15 available to them different dissolution testing
16 methods other than USP 711?

17 A I mean, I'm not sure. I mean, if
18 they're doing the standardized dissolution test
19 method that is in USP 711, it is quite clear
20 what they are doing. So I can't think that
21 they're following any other -- that's nothing
22 else other than the same as the USP 711.

1 Q But you agree that Cole doesn't
2 actually say it is using USP 711, right?

3 A Well, whether they say or not, that's
4 what they are using.

5 Q Where do you --

6 A Because --

7 Q I'm sorry, go ahead.

8 A It's exactly the same.

9 Q Where do you say that in your
10 declaration? I think -- and correct me if I'm
11 wrong, please -- all you say in paragraph 136 is
12 that USP 711 was "the most common method for
13 dissolution testing," and, as a result, that's
14 what a person of skill in the art would
15 understand Cole was using. Do you point to
16 anything specific in Cole?

17 A Yes, I do. The actual method itself.

18 Q Which is what?

19 A Two hours of pH 1.2 and then
20 elevation of the pH and then determination of
21 the drug concentration. It's exactly the same
22 method.

1 Q Are there other aspects to USP 711
2 other than the things that you have written in
3 paragraph 136?

4 A For the enteric dissolution test, no.

5 Q Are there specific --

6 MR. MILEA: Withdrawn.

7 Q Are there other different procedures
8 or equipment that are specified in USP 711 that
9 are not referenced in paragraph 136 of your
10 declaration?

11 A I think if we really want to dig down
12 into this, we'd need to pull Cole up and look at
13 the actual methodology they have used. I've
14 paraphrased the dissolution method as one would
15 understand this to be a standardized dissolution
16 method that Cole is using to test an enteric
17 formulation.

18 Q Earlier we discussed whether the
19 USP 711 method available in 2001 and 2002 was
20 different than the USP 711 method in 2017.

21 Do you recall that discussion?

22 A Well, I recall that you asked a

1 question about it, and I said I didn't think
2 there was any difference.

3 Q I'm going to mark a new exhibit as
4 Exhibit 2050, and it should, hopefully, be in
5 the PGR repository labeled as "Brown.pdf."

6 REMOTE TECH: Stand by.

7 (McConville Exhibit 2050 marked for
8 identification and attached to the transcript.)

9 A Okay, I've got that.

10 Q Exhibit 2050 is a document entitled,
11 "USP and Dissolution--20 Years of Progress," and
12 it is authored by William E. Brown and
13 Margareth R. Marques.

14 Do you see that?

15 A Yes.

16 Q Have you ever seen this document
17 before?

18 A I might have. Maybe. I can't recall
19 it offhand, no, but I possibly have glanced at
20 it.

21 Q There's a few specific portions of
22 the document I would like to talk about. If you

1 need to read other parts, just let me know, but
2 I want to talk about, on the second page, which
3 is, if you use the page number on the bottom
4 right, page 25. In the left-hand column there
5 is a section called "Harmonization"?

6 A Yes.

7 Q Near the end of that paragraph there
8 is a sentence that says, "The harmonized
9 dissolution chapter in USP was made official on
10 April 1st, 2006, in USP 29."

11 Do you see that?

12 A Yes.

13 Q Do you agree that when that
14 harmonization --

15 MR. MILEA: Withdrawn.

16 Q Do you agree that when that --

17 MR. MILEA: Withdrawn.

18 Q Do you agree that the harmonized
19 dissolution chapter would have changed?

20 MR. MILEA: Withdrawn.

21 Q Do you agree that there would have
22 been changes to the dissolution chapter when it

1 was harmonized in 2006?

2 A What type of changes?

3 Q Well, let's -- what does
4 harmonization mean in the context of a USP
5 procedure?

6 A Well, as you can see, it is
7 related -- as you look at the top of the
8 paragraph, it is related to International
9 Pharmaceutical Federation (FIP). And there's
10 actually several pharmacopeias around the world.
11 There is the Japanese pharmacopeia, there is the
12 European pharmacopeia, there is the British
13 pharmacopeia and then there is the United States
14 pharmacopeia.

15 One of the main goals of
16 harmonization was just to make sure that the
17 text was universally the same in all the
18 pharmacopeias.

19 Q And so that would mean that if there
20 were differences between the different
21 pharmacopeias from the different countries,
22 changes would need to be made to make sure they

1 matched up with one another to harmonize them;
2 is that fair?

3 A Well, from a layout perspective more
4 so than anything else, not the actual physical
5 tests themselves, this harmonization process was
6 related to reorganization of the text more than
7 anything else, as far as I understand.

8 Q Do you know whether there were any
9 changes to the test procedures themselves done
10 as part of this 2006 harmonization procedure?

11 A Specifically, I would say not to my
12 understanding related to the enteric dissolution
13 test, nothing -- nothing of consequence, anyway.

14 Q But there were changes to the enteric
15 dissolution test between 2001 and 2017 as a
16 result of this harmonization; is that fair?

17 A I would say nothing of consequence.

18 Q But you agree there were changes?

19 A I don't know. Well, let's put it
20 this way. For sure, there was nothing of
21 consequence from any change that may have
22 occurred. Generally, changes were related to

1 organization of the paragraphs and that's as far
2 as I think it went. I think the chapter number
3 might have changed. Perhaps the numbering
4 system changed slightly. I do not believe there
5 was any change in the actual test procedure that
6 would have had any consequence to dosage form
7 analysis.

8 Q Do you see in the last sentence of
9 this harmonization paragraph that we are looking
10 at on page 25 of Exhibit 2050, it says, "A
11 change to the description of the wire mesh used
12 in basket construction was added as a revision
13 to the harmonized document and published in
14 USP 34 in 2011"?

15 A Okay.

16 Q Is that at least one change that was
17 made to USP 711 between 2002 when Cole was
18 published and 2017, which is the priority date
19 of the '391 patent?

20 A A change in description is what I
21 see, yes. So rewording, that's how my
22 understanding of a change in description,

1 rewording.

2 Q Is it possible that there were other
3 changes to the USP 711 procedure between 2002
4 and 2017 that are not mentioned in this
5 paragraph in Brown?

6 A Well, I mean, that's, you know, a --
7 let me see. It is a description of one change
8 related that to the wire mesh. Maybe there were
9 other minor changes too.

10 Q And that's not something you
11 accounted for in your declaration; is that fair?

12 A I don't think it's really relevant.

13 Q And it's not in your declaration; is
14 that right?

15 A Because it's not relevant.

16 MR. MILEA: Okay, I don't have any
17 further questions at this time. Thank you very
18 much, Doctor. I really appreciate it.

19 THE WITNESS: Thank you.

20 MR. MAHON: Nothing for us.

21 MR. MILEA: Okay, well, thank you
22 very much. I hope everybody has a nice

1 afternoon -- or is it still morning? No, it is
2 afternoon in New Mexico. So I hope you have a
3 nice afternoon, Doctor.

4 THE WITNESS: Thank you very much.
5 You, too.

6 (Time noted: 2:08 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I, JASON McCONVILLE, Ph.D., do hereby
acknowledge that I have read and examined the
foregoing testimony, and the same is a true,
correct and complete transcription of the
testimony given by me and any corrections appear
on the attached Errata sheet signed by me.

(Date)

(Signature)

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2

3 I, ADRIENNE MIGNANO, Registered
4 Professional Stenographic Reporter and Notary
5 Public do hereby certify:

6 That JASON McCONVILLE, PH.D., the
7 witness whose deposition is hereinbefore set
8 forth, was duly sworn by me before the
9 commencement of such deposition and that such
10 deposition was taken before me and is a true
11 record of the testimony given by such
12 witness.

13 I further certify that the adverse
14 party, INTAS PHARMACEUTICALS LTD was represented
15 by counsel at the deposition.

16 I further certify that the deposition
17 of JASON McCONVILLE, PH.D., occurred remotely
18 via Zoom Videoconference equipment on Friday,
19 January 16, 2026, commencing at 11:00 A.M. to
20 2:08 P.M.

21 I further certify that I am not
22 related to any of the parties to this action by

1 blood or marriage, I am not employed by or an
2 attorney to any of the parties to this action,
3 and that I am in no way interested, financially
4 or otherwise, in the outcome of this matter.

5 IN WITNESS WHEREOF, I have hereunto set my
6 hand this 20th day of January 2026.

7 My commission expires:

8 June 2026.

9 

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11 ADRIENNE M. MIGNANO, RPR

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