

Transcript of Rodolfo Pinal, Ph.D.

Date: April 26, 2024
Case: Hopewell Pharma Ventures, Inc. -v- Merck Serono, S.A. (PTAB)

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Merck 2080
Hopewell v Merck
IPR2023-00480

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.

Petitioner,

v.

MERCK SERONO S.A.,

Patent Owner.

IPR2023-00480
U.S. Patent 7,713,947
IPR2023-00481
U.S. Patent 8,377,903

Deposition of RODOLFO PINAL, PH.D.

Washington, D.C.

Friday, April 26, 2024

9:03 a.m.

Job No. 534629

Pages 1 - 134

Reported by: Karen Young

Deposition of RODOLFO PINAL, PH.D., held at the offices of:

STERNE, KESSLER,
GOLDSTEIN & FOX, P.L.L.C.
1101 K Street, Northwest
Washington, D.C. 20005
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Pursuant to notice, before Karen Young, Notary Public of the District of Columbia.

A P P E A R A N C E S

ON BEHALF OF HOPEWELL PHARMA VENTURES, INC.:

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ALSO PRESENT:

Emil White, Remote Technician

C O N T E N T S

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EXHIBITS REFERRED TO
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Exhibit 1013 Paper by Stelmasiak et al..... 98
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(Exhibits were marked prior to the deposition.)

P R O C E E D I N G S

RODOLFO PINAL, PH.D.,

having been duly sworn, was examined as follows:

- - -

EXAMINATION BY COUNSEL FOR MERCK SERONO S.A.

BY MR. BERTULLI:

Q Good morning, Dr. Pinal.

A Good morning.

Q Thank you for joining us today.

A Thank you.

Q You understand that you're under oath today?

A I do.

Q Is there any reason that you cannot provide complete and truthful testimony today?

A There is no reason.

Q Okay. And -- well, let me ask you this question. You understand that today's deposition is covering two IPR proceedings, right?

A That is my understanding.

Q And it's not a quiz, but one of them is

IPR2023-00480. Does that sound right?

A That sounds right.

Q And I see that you've consulted a document to answer my question. What is that document you've got there with you?

A The document I'm holding in my hands right now is a copy of my declaration on IPR2023-00480.

Q And does that copy of your declaration have an exhibit number in the bottom right-hand corner on the cover?

A It does.

Q And what's that number?

A The number is EX1080.

Q Okay. And then the other proceeding that we're covering today is IPR2023-00481. Is that also your understanding?

A That is also my understanding.

Q Okay, and you've also consulted a hard copy of your declaration in that second proceeding; is that right?

A Correct.

Q And does it have an exhibit number in the lower right-hand corner?
A It does.
Q And what's that number?
A EX1080.
Q Do you have any other hard copies of documents with you today?
A The only hard copies of documents that I have with me today are the two documents for which I read the exhibit number for you.
Q Your declarations.
A That is correct.
Q Are those clean copies of your declarations?
A Both copies are clean. There are no annotations by anyone on either of them.
Q Great. Do you recall when you were contacted to participate in this case?
MS. KHANDURI: Objection. Dr. Pinal, I will remind you to -- I will caution you to not divulge the substance of communications with counsel. Subject to that instruction, you can

answer the question.

A I have a recollection of being contacted for the first time to work on this case.

Q Do you recall when that was?

A Not precisely.

Q Do you have an estimate of when that was?

A A good estimate that I would give is a few months ago.

Q A few months ago? And that's a few months ago from today, April 26th, 2024.

A A few months prior to April 26th, 2024.

Q And without sharing any content of any privileged communications, do you recall who reached out to you to participate in this case?

A I do.

Q Who was that?

A Ms. Bond.

Q Who is Ms. Bond?

A Ms. Bond is a person that works at the firm that I'm working with.

Q Okay, and that firm's Sterne Kessler?

A That is correct.

Q Okay. How many times have you provided a declaration in an inter partes review proceeding before this case?

A I cannot give you a precise number, but I know that there is at least one.

Q Less than ten times?

A Less than ten times would be an adequate estimate.

Q And do you recall how many times, if any, you've given deposition testimony before today?

A Deposition testimony in general or for IPR proceedings?

Q That was going to be my next question. So you can answer in general, and then we can break it up if that would be helpful, but how about generally first, how many times have you sat for a deposition?

A In general, about 15 times.

Q And to your point of clarification, how many of those times were for an inter partes review proceeding?

A To the best of my recollection, this is

the first time that I'm deposed on a IPR proceeding.

Q Okay, so for the rest of those 15 depositions, were those District Court litigations that you gave testimony for?

A I don't know the specific legal situations, but I would say that I believe so.

Q Has every deposition that you've participated in been with regard to a patent dispute?

A I believe so.

Q Let's -- I'm going to ask you questions about your declaration shortly, but some more housekeeping. Did you prepare for today's deposition?

MS. KHANDURI: I will caution the witness not to divulge the substance of the communications with counsel. Subject to that instruction, you can answer the question.

A I did.

Q Yes or no, did you prepare with counsel?

A My preparation for this deposition

included meeting with counsel.

Q The part of your preparation that included meeting with counsel, did that take place in one meeting?

A It did not.

Q How many meetings did your -- strike that. How many times did you meet with counsel to prepare for your deposition?

A My estimate is about five times.

Q Did all five meetings with counsel take place in person?

A They did not.

Q How many of the five meetings with counsel took place in person?

A Three.

Q Without disclosing any privileged communications or the content of your discussions, which counsel was present for your preparation for this deposition?

A The three attorneys here present.

Q Was anyone else who was not an attorney present for your preparation?

A There was no one else other than the three attorneys here present.

Q And is that true for all five meetings that you conducted to prepare for today's deposition?

A It is true for the three meetings we had in person. To the best of my knowledge, it was also true for the meetings we have video conference.

Q Understood. And so what preparation did you do for your deposition that did not include meeting with counsel?

A It included reading my declaration and reviewing the materials considered for the most part.

Q What do you mean by for the most part?

A It also involved thought process of connecting concepts.

Q Did you speak with anyone besides counsel during your preparation?

A I have not spoken with any person other than counsel as part of my preparation.

Q Have you ever spoken with anyone other than counsel about this case at all since you've begun working on it?

A I have not spoken about this case with anybody outside counsel.

Q Why don't you pick up your copy of Exhibit 1080, which I think is your declaration in the IPR2023-00480 proceeding.

A I have it in front of me.

Q And if I could ask you to please turn to page 45? That's the very end. Are you there?

A I am there.

Q Okay, and page 45 of your declaration shows your signature. Do you see that?

A I see it.

Q Is that your signature?

A That is my signature.

Q And you signed this declaration on April 3rd, 2024.

A That is correct.

Q Okay, and I'm hoping to just have us stick with one declaration so you're not jumping

back and forth all day, but if you go to your other declaration in the 00481 proceeding --

A I have it in front of me.

Q Can you please go to the last page there?

A I am on the last page.

Q And does the last page of your second declaration also bear your signature?

A This is also my signature.

Q And you signed it?

A I did sign it.

Q And you signed it on April 3rd, 2024.

A I signed it on April 3rd, 2024.

Q And you said you reviewed your declarations as part of your preparation; is that right?

A That is correct.

Q Are there any opinions in either of your declarations that you'd like to change today?

A The opinions presented in my declarations have not changed as of this moment.

Q So each of your opinions contained in your declarations are true and correct to the best

of your understanding.

A To the best of my understanding, they are true and correct.

Q Are you equally confident in every one of your opinions?

A Could you clarify the question?

Q Sure. So each of your declarations includes more than one of your opinions. Is that fair?

A My declaration contains different aspects of my general opinion.

Q And are you equally confident in every aspect of your opinions in your declarations?

A All the opinions that I present as part of my general opinion represent my level of confidence on them.

Q Why don't we stick with the Exhibit 1080 declaration in the 00480 case, okay?

A Okay.

Q Could you please turn to page 8?

A I am on page 8.

Q At paragraph 21, you write, "In

formulating my opinions, I considered the following documents." Do you see that?

A I see it.

Q And then there is a table that reads from the bottom of page 8 it looks like all the way through pages 9, 10 and 11. Do you see that table?

A I do.

Q Did you consider any documents in formulating your opinions that are not included in this table?

A The documents considered in forming my opinion are listed on this document.

Q And you considered every document that's listed in this table?

A I read and considered every document in forming my opinion.

Q Okay, so looking at the bottom of page 8, do you see an Exhibit Number 1002?

A I see it.

Q And the description of that exhibit reads, "Declaration of Aaron Miller, M.D." Did I read that correctly?

A You did.

Q So in formulating your opinions in your declaration, you considered Dr. Miller's declaration, Exhibit 1002; is that right?

A I did consider Dr. Miller's declaration.

Q Did you agree with all of the opinions that Dr. Miller set forth in Exhibit 1002?

MS. KHANDURI: Objection, scope.

A My opinion as per what I was asked to opine on refer to the formulation and the dosage form and the times of treatment regimen without extending to the therapy of multiple sclerosis.

Q Did Dr. Miller's declaration of Exhibit 1002 include any opinions as to formulation?

A Could I have a copy of Dr. Miller's declaration?

Q I'm just asking you questions about your review. You reviewed it, right?

A I review it. I did not memorize it.

Q Okay. Do you recall if Dr. Miller provided any opinions about formulation in his declaration?

A Could I have a copy of Dr. Miller's declaration?

Q I just asked if you recalled, and I hear you requesting a copy, but your deposition's not about Dr. Miller's declaration. It's about your declaration and your review of Dr. Miller's declaration.

A As I sit here right now, I cannot give you a precise recollection of what I read in Dr. Miller's declaration.

Q Do you think that if you had read something in Dr. Miller's declaration that you disagreed with, you would have remembered it?

MS. KHANDURI: Objection, form, foundation.

A I don't understand your question.

Q Well, you read Dr. Miller's declaration, Exhibit 1002; is that right?

A That is correct.

Q So in your reading it, if you had encountered something that you disagreed with in his declaration, would that have stuck with you?

MS. KHANDURI: Objection, form, foundation.

A Dr. Miller's declaration bases on the therapy of multiple sclerosis for a person of skill in the art who had chosen to utilize cladribine. I have not been asked to opine on that subject, and as such, I don't disagree. I have no reason to disagree with Dr. Miller's opinion.

Q Okay, so that's fair. So then let me ask it this way. You don't have any reason to dispute anything that was included in Dr. Miller's declaration of Exhibit 1002. Is that fair?

A I have found no reason to dispute the opinions of Dr. Miller.

Q What is your understanding of Dr. Miller's expertise?

A Could I have a copy of Dr. Miller's declaration?

Q Do you need a copy of Dr. Miller's declaration to identify your understanding of his expertise?

A I have not memorized Dr. Miller's

declaration.

Q Dr. Miller's a neurologist; is that right?

A I have not memorized the career path of Dr. Miller.

Q Have you ever talked to Dr. Miller?

A I have not.

Q Have you ever communicated with Dr. Miller through other electronic means like e-mail or text message?

A I have not.

Q Has Dr. Miller ever consulted with you with respect to this case?

A He has not.

Q Are you aware if Dr. Miller has submitted any other declarations in support of this case?

A I am aware that Dr. Miller submitted, to the best of my knowledge, two declarations.

Q Have you ever seen Dr. Miller's second declaration in this case?

A I have not.

Q So you did not see Dr. Miller's second

declaration at the time that you signed your declaration in this case.

A I did not.

Q Do you know if Dr. Miller has ever reviewed your declaration in this case?

A I don't have direct or firsthand knowledge on the answer to that question.

Q And that's totally fair. I just want to know if you know. Who knows what he's done on his own or otherwise. Just you, do you know if Dr. Miller has ever reviewed your declaration in this case?

A To my knowledge, I don't know.

Q In your declaration, can you please turn to paragraph 13?

A I have paragraph 13 in front of me.

Q You are an expert in the field of pharmacology; is that right?

A I refer to myself as a pharmaceutical scientist, and as such, pharmacology is one of the subjects of my expertise, but it is not the only one.

Q Is pharmacokinetics an aspect of your expertise in pharmacology?

A Pharmacokinetics is a subset of the pharmaceutical sciences, like pharmacology. It is part of the expertise of a pharmaceutical scientist.

Q Are you comfortable if I refer to pharmacokinetics today as PK?

A I will be comfortable with that.

Q Is formulation an aspect of PK?

A Formulation is another subject that falls under pharmaceutical sciences.

Q So -- so that I understand, so formulation falls outside the scope of PK specifically?

A In the pharmaceutical sciences, the different subjects or sub-subjects are interconnected, but they have somewhat different focus because each one covers a slightly different aspect.

Q So what is, in your words, formulation?

MS. KHANDURI: Objection, form.

A Formulation in the pharmaceutical context is the design of -- the design, preparation, manufacture of compositions used in pharmaceutical processes.

Q And how does formulation factor into the design, preparation and manufacture of compositions used in pharmaceutical processes?

A Can you repeat your question please?

Q Sure. How does formulation factor into the design, preparation and manufacture of compositions used in pharmaceutical processes?

MS. KHANDURI: Objection, form, scope.

A I absolutely don't understand your question.

Q Okay. What is drug absorption in the context of pharmaceutical sciences?

A In the context of pharmaceutical sciences, drug absorption is the process that follows administration of a drug into a subject or patient such that the drug, for lack of a better term, gets incorporated, not to be redundant with the word "absorption," into the body of the

subject.

Q And you looked at drug absorption as part of your analysis in this case; is that right?

A Drug absorption is one of the phenomena involved in considering the attributes of pharmaceutical formulations and pharmaceutical products.

Q In the context of pharmaceutical sciences, what is solubility?

A Solubility is a property of chemical substances that refers to the maximum concentration that can be achieved for a given substance in a liquid solution.

Q And you looked at solubility as part of your analysis in this case. Is that true?

A The solubility phenomenon is part of the parameters that are taken into account when considering pharmaceutical products or pharmaceutical dosage forms.

Q And you would have taken solubility into account in your analysis in this case.

A Solubility is one of the parameters that

is taken into account.

Q Is permeability another parameter that would have been taken into account in your analysis in this case?

A Permeability is another parameter that is taken into account when considering pharmaceutical products or pharmaceutical dosage forms.

Q And what is permeability in this context?

A Permeability can be put as the ability of a molecule, in this case a drug molecule, to penetrate tissues of the body of the subject to whom a drug has been administered.

Q Is dosage form another parameter that you would have taken into account in your analysis in this case?

A Could you clarify your question?

Q Sure. Well, are you familiar with the phrase "dosage form"?

A I am, and that is why I'm asking you to clarify your question.

Q Well, what does dosage form mean to you in the context of pharmaceutical sciences?

A Dosage form is the physical form, for example, a tablet or a capsule, which is used to administer a formulation to a patient or subject.

Q Were you consulting a particular paragraph of your declaration while arriving at your answer?

A I was consulting a footnote.

Q Which footnote was that?

A It is footnote number 2.

Q You mentioned tablets and capsules as examples of dosage form; is that right?

A In my previous answer, those are the two terms that I used.

Q Is a solution another example of dosage form?

MS. KHANDURI: Objection, form.

A Dosage forms include solutions.

Q Is sublingual film an example of a dosage form?

MS. KHANDURI: Objection, form.

A Dosage forms include sublingual films.

Q Did you analyze any examples of

sublingual films as part of your analysis in this case?

A I have no precise recollection of that.

Q Can you describe what a sublingual film is?

A I can.

Q Could you please?

A A sublingual film in general terms is a thin layer of a material, typically polymeric material or a material that has the ability to form films, and in that thin layer, a drug is embedded, and that piece of material is placed in the mouth cavity, and if it is sublingual, it is under the tongue, and when placed in there, that is how it is administered.

Q Do you recall when you first encountered sublingual films in your work in the field?

MS. KHANDURI: Objection, scope.

A I don't recall when I first encountered sublingual films in my work.

Q Do you have any understanding of when sublingual films were first developed in

pharmaceutical sciences?

MS. KHANDURI: Objection, scope.

A The subject of sublingual -- sublingual films has been around for many years in the pharmaceutical sciences, so if you can be more specific in your question, I may be able to answer.

Q What do you mean by many years in your answer?

A The reason I do not recall exactly when I first encountered sublingual films is that to the best of my recollection, it happened at some time when I was a student, so your question about some specific development of films, if I'm able to answer it, I need you to be more precise in your question.

Q Okay. Well, we can come back to that because I have a few other parameters that I want to cover. What does it mean if a drug or a compound is in an amorphous form?

MS. KHANDURI: Objection, form, foundation.

A The amorphous form of a material is one

in which the crystalline composition of that material has been disrupted.

Q What do you mean when you say the crystalline composition of that material has been disrupted?

A When a material such as a drug substance, which almost as a rule are produced in crystalline form, meaning as crystals, when that crystalline arrangement is ameliorated so that it's no longer present, the material takes the amorphous form.

Q Is stability another parameter considered in the pharmaceutical sciences?

MS. KHANDURI: Objection, form, foundation.

A The stability of drugs is one consideration in the development of pharmaceutical drugs.

Q In the context of pharmaceutical drugs, what is stability?

A In the context of the pharmaceutical sciences and the pharmaceutical field, stability is the capacity of a drug in a drug product to remain

chemically intact for a prolonged period of time.

Q Is higher stability for a drug preferable?

MS. KHANDURI: Objection, form, foundation.

A With everything else equal, if the drug lasts longer chemically intact in one product as opposed to another product, the one that lasts chemically intact longer would be preferable.

Q Which form of drug has a hire stability, amorphous or crystalline?

MS. KHANDURI: Objection to form.

A It depends.

Q On what?

A It depends on what the environment of the amorphous drug happens to be.

Q What aspects of the environment of the amorphous drug are considered when looking at stability?

A One of the aspects that is considered when looking at a stability is the presence and effect of other ingredients in the formulation.

Q And what do you mean by other ingredients?

A Pharmaceutical products contain an active compound, which is the drug. It is the main use in the field. They also contain other ingredients which are not pharmacologically active.

Q So you called the -- the drug in a -- I'm sorry, strike that. You called the drug the active compound? Am I following that correctly?

A That is a common term used in the pharmaceutical field, so can be used with the word "drug" or the word "active compound" to refer to the pharmacologically active compound, which is the drug.

Q Is there a common term used in the pharmaceutical field to refer to the other ingredients which are not pharmacologically active?

A There is.

Q What's that term?

A The term used for non-pharmacologically active ingredients in pharmaceutical products is excipient.

Q A few moments ago, you talked about tablets. When -- when studying dosage form, does the size of a tablet matter?

A Can you clarify your question please?

Q Sure. Well, let me ask it differently. I guess if all else being equal, if a pharmacologist is developing a tablet, do they -- does that person consider the size of the resultant tablet at all?

MS. KHANDURI: Objection, form, foundation.

A With everything else equal, tablets are made taking into consideration the person who is going to use them. In that sense, the size of the tablet is something that can be handled by the patient with ease, and it can also be swallowed by the patient with ease.

Q So that's a helpful clarification. I was going to ask you if when you said handled by the patient with ease, if you meant swallowing it, but I think it means something different.

A Patients, when they have to take

medication, they need to grab with their hands their medication, and subsequently, take it, ingest it. So aspects of holding them in hand is something that is relevant to the use of medications.

Q So it seems like a smaller sized tablet could be harder to handle for certain types of patients.

MS. KHANDURI: Objection, form.

BY MR. BERTULLI:

Q Is that fair?

A Can you clarify?

Q Yeah.

A What kind of --

Q I'm just trying to explore this. I have had many small pills myself that I've dropped down the sink and I didn't mean to, so I'm thinking as you're describing this that a smaller pill like a tiny pill would be harder to handle, and I think that's what you're getting at when you say that one aspect to consider is how the patient handles the tablet?

MS. KHANDURI: Objection to form, scope.

A The physical design of a tablet takes into account several factors. One of them is the ability to swallow. The other one is the ability to handle, among other things.

Q And when we -- when you talk about the ability to swallow a pill, is it fair to say that a large size pill might be harder for a human patient to swallow?

MS. KHANDURI: Objection, scope, form.

A Can you define what do you mean by large size?

Q Well, sure. So I mean, this may sound casual, but like have you heard the term a horse pill?

A I have.

Q So as a layman in this field, when I hear "horse pill," I think of a large sized pill for horses. Is that what a horse pill is?

MS. KHANDURI: Objection, form.

A I have seen veterinary tablets, but I cannot recall if they were for horses or not.

Q Were the veterinary tablets that you have seen large in size?

A They were larger than the traditional pills that you find for human use.

Q Do you think that pills that are the size of a veterinary tablet are desirable in size for human use?

MS. KHANDURI: Objection, form, foundation.

A I don't want to get into speculations. That is not what I'm here to do, but it's not what I've been asked to do, and that's something that I would rather not do. To answer your question is there is a range of sizes that is adequate for humans, and that is known in the pharmaceutical industry. There is a range of sizes that is adequate for cows, and that is known in the pharmaceutical industry, and I could go on with other species.

Q What about going -- and let me pause there. I see we've been going for about an hour. Let me ask you a couple more questions about dosage

form, and then do you want to take a break?

A I would like to take a break.

Q Like right now or a couple more questions?

A I would leave it up to you.

Q Okay, I'll try to be quick. Going the other direction, you're familiar with pill cutters, right?

MS. KHANDURI: Objection, scope.

A I am.

Q And what is your understanding of what a pill cutter is?

A A pill cutter is a device that in very simple terms has the blade and a lever and then rotational -- like a hinge type of thing, and it is used to cut -- cut it.

Q Do you think that having to use a pill cutter to cut a tablet would contribute to the convenience for a patient to take that tablet?

MS. KHANDURI: Objection, scope, form.

A That would be a question that the patient would be able to answer.

Q That wouldn't be a question that you as the pharmacologist would consider?

A The tablet cutter was created to be used in concert with a scoring in dosage forms.

Q And I think I know what you mean, but just so that we're on the same page, when you say the scoring in dosage forms, what do you mean by scoring?

A The physical scoring seen in dosage forms.

Q So like if I had a pill in my hand that had a little line across the center of it, that's the scoring you're thinking of?

MS. KHANDURI: Objection, form, scope.

A The term used for those lines is scoring.

Q What if a patient had to use a pill cutter to cut a pill somewhere else on the pill that wasn't where the scoring was?

MS. KHANDURI: Objection, form.

BY MR. BERTULLI:

Q Do you have that in mind?

MS. KHANDURI: Objection, scope, form.

A I have not been asked to speculate, and I would rather not get to speculate on the improper use of pill cutters or dosage forms. That is not what I am here to opine on.

Q So if a patient had a tablet that was scored and the patient needed to cut the tablet elsewhere on the pill, that would be an improper use of the pill cutter?

MS. KHANDURI: Objection, scope, form.

A It could be.

Q Okay, and one more question on this and then I think we can go to the break. So in your opinion as a expert in the field of pharmacology, do you think patients prefer to take one pill or multiple pills for a single dose of a drug?

MS. KHANDURI: Objection, form, scope, foundation.

A I have not look at data on survey regarding that subject, so I cannot give you a precise answer.

Q Do you have a view as a pharmacologist one way or the other?

MS. KHANDURI: Objection, form, scope, foundation.

A With everything else equal, we can expect that patients would have a preference taking a particular drug in one unit as opposed to two, but it doesn't mean it is a rule.

Q Right, not a rule, but a preference.

MS. KHANDURI: Objection, form, scope.

THE WITNESS: It could be a preference or it could not be a preference or it could not make a difference, so it depends.

MR. BERTULLI: Okay, why don't we go ahead and take a break.

THE WITNESS: Okay.

(Recessed at 10:07 a.m.)

(Reconvened at 10:21 a.m.)

BY MR. BERTULLI:

Q Welcome back, Dr. Pinal.

A Thank you.

Q I have a few more questions about parameters that you might consider in analyzing pharmacokinetics, okay? What is the route of

administration?

A Route of administration is a term used to refer to the part of the body through which a pharmaceutical product is delivered to a subject or patient.

Q Is one example of a route of administration oral delivery --

MS. KHANDURI: Objection to form.

BY MR. BERTULLI:

Q -- of pharmaceutical product?

MS. KHANDURI: Objection, form.

A Oral delivery is one route of administration for pharmaceutical products.

Q Is oral delivery a common route of administration for pharmaceutical products?

A Oral delivery is frequently used to administer pharmaceutical products.

Q Are there any other routes of administration that are frequently used to administer pharmaceutical products?

A Would you clarify to me how do you define frequently in this context?

Q Well, I'm using your words. So you said oral delivery is frequently used to administer pharmaceutical products. Do you recall that testimony a moment ago?

A I do.

Q So I was just asking if there are other routes of administration that are frequently used to administer pharmaceutical products.

A Yes, there are.

Q Can you name them please?

A One route of administration that is frequently used is injection, for example.

Q Did you consider injection in your analysis in this case?

MS. KHANDURI: Objection, form.

A From what perspective are you asking if I considered injection?

Q As an expert in the field of pharmacology rendering your opinion in this case.

A Do you refer to injection as the -- as a route of administration or injection as a procedure?

Q I refer to injection as a route of administration in this question.

MS. KHANDURI: Objection, form.

A As part of my knowledge in pharmaceutical sciences, the route of administration includes the different routes of administration. For specific purposes such as pain, I was asked to opine on oral route of administration.

Q So as part of your analysis in this case, you did not opine on any other route of administration other than oral; is that right?

MS. KHANDURI: Objection, form, foundation.

A As part of my analysis, the oral and injectable routes of administration were considered.

Q Bioavailability is another parameter considered in the study of pharmacokinetics; is that right?

MS. KHANDURI: Objection, form, foundation.

A Bioavailability is a parameter in the

area of pharmacokinetics.

Q What is absolute bioavailability?

MS. KHANDURI: Objection, foundation, form.

A Absolute bioavailability is a measure of the systemic availability of a drug in the systemic circulation referred to the availability of the drug after -- or obtained from intravenous administration.

Q And what is relative bioavailability?

MS. KHANDURI: Objection, form, foundation.

A Relative bioavailability is a measure of the -- of availability of a drug in the systemic circulation relative to the availability of a drug in the systemic circulation produced by a standard type of product or composition that is not administered by the intravenous route.

Q And bioavailability is generally expressed as a percentage; is that right?

MS. KHANDURI: Objection, form, foundation.

A A common way of expressing bioavailability is a percentage, is the ratio of two values.

Q So what is the difference between absolute bioavailability and relative bioavailability?

MS. KHANDURI: Objection, form, foundation.

A The difference between the two terms is what is the reference value. In absolute bioavailability, the reference is the intravenous administration values. In relative, bioavailability is -- the reference is some product that is for the purpose of the study considered the standard that need not be administered intravenously.

Q And in the field generally with bioavailability, the higher the better; is that right?

MS. KHANDURI: Objection, form.

A With everything else equal, having higher bioavailability would be considered preferable.

Q Interpatient variability is another parameter considered in the area of pharmacokinetics; is that right?

MS. KHANDURI: Objection, form, foundation.

A Interpatient variability is an aspect that is part of studies on pharmacokinetics, and as such, is something that is considered.

Q And you considered interpatient variability as part of your analysis in this case, right?

MS. KHANDURI: Objection, form, foundation.

A I include my consideration and opinions regarding interpatient variability in my declaration.

Q And in general, as to interpatient variability, the lower the better, right?

MS. KHANDURI: Objection, form.

A In general, lower variability is preferable.

Q Going back to bioavailability for a

second, can formulation affect bioavailability?

MS. KHANDURI: Objection, form, foundation.

A Formulation is one of the aspects that can have an impact on variability.

Q Can you have different formulations of the same drug?

A For any particular drug, it is possible to make different formulations.

Q What aspects of those formulations of the same drug makes them different?

MS. KHANDURI: Objection.

BY MR. BERTULLI:

Q Yeah, maybe that's a weird question.

A Would you mind --

Q Yeah, you took off your glasses. That one troubled you. So it's possible to make different formulations of the same drug. We agree?

A It is possible to make different formulations of the same drug, that's correct.

Q So can you give me an example of something that would be different about those

formulations of the same drug, like a certain parameter or characteristic?

MS. KHANDURI: Objection, form.

A I think so.

Q Can you please give me one?

A Changing the composition would be a change in formulation.

Q Is -- is changing the composition of the active component a change to the formulation?

A Sorry.

Q I know everyone's enjoying these questions in the room.

A That doesn't make sense.

Q Okay. What's wrong with it?

A By changing the active --

Q That screws it all up?

A Let me see how I can phrase it. By changing the active, we have a different molecule, we have a different drug. The formulation doesn't matter because it's a completely different thing. There is no -- there's a different molecule, so I'm looking for the words, but I think I'm --

Q So we shouldn't change the active component is --

MS. KHANDURI: Objection.

BY MR. BERTULLI:

Q -- I think what you're telling me.

MS. KHANDURI: Objection, form.

A For a drug that has been selected for a particular therapeutic application and for treating a specific condition, changing the drug is -- it would put it in balance the same as changing the condition, so if we change the drug in the formulation, it would be the same as if we were changing the disease that is being treated.

Q Got it. What about changing the excipient aspect of the drug?

MS. KHANDURI: Objection, form, foundation.

A By changing the excipients in a composition, that would be one way of changing the formulation.

Q Okay. Can two different formulations of the same drug have different bioavailability?

MS. KHANDURI: Objection, form.

A It is possible for two different formulations of the same drug to have different bioavailability.

Q Is lymphocyte suppression another parameter studied in the area of pharmacokinetics?

MS. KHANDURI: Objection, form, foundation.

A Pharmacokinetics deals with the, for lack of a better term, fate of the drug in the body. Lymphocyte suppression is a pharmacological effect, so pharmacokinetics does not extend to the pharmacological effect.

Q So what kind of expertise would a person who would study the lymphocyte suppression have?

MS. KHANDURI: Objection, form, scope, foundation.

A Lymphocyte suppression, being a pharmacological effect, it falls within the realm of the medical and pharmaceutical sciences.

Q So does the analysis of lymphocyte suppression fall into your area of expertise?

MS. KHANDURI: Objection, form.

A The pharmacological effect of drugs and drug products is information that is considered when developing pharmaceutical products. The analysis in terms of the pathological condition is more to the clinical side and medical profession.

Q We've talked about a number of PK parameters this morning. Now I guess I want to ask a couple of questions about how those parameters are reported. So in the context of PK parameters, what is an average value?

MS. KHANDURI: Objection, form, foundation.

A It depends.

Q On what?

A On the particular type of calculation that is being used.

Q What do you mean by particular type of calculation that is being used?

A In some instances, the average is the arithmetic mean, but in some others, what is used is the geometric mean.

Q And what is a geometric mean?
A The geometric mean is the product of all the observations raised to the inverse power of the number of observations.
Q Can an arithmetic mean and a geometric mean ever result in the same number?
MS. KHANDURI: Object to form.
A It is possible.
Q In the context of PK parameters, what is a standard deviation?
A Standard deviation in the context of pharmacokinetic parameters has the same definition as in the context of traditional statistics.
Q And what is that definition?
A It is the summation of each observation subtracting the mean raised to the square power divided by the number of observations minus one and the square root of that ratio.
Q How is a standard deviation used in the context of pharmacokinetic parameters?
A Standard deviation is a measure of the variability of the observations.

Q In the context of PK parameters, what is a range of values?

MS. KHANDURI: Objection, form.

A In the context of pharmaceutical -- pharmacokinetic parameters, a range for response to two values that the investigators report as being the -- I don't want to repeat the word "range," but the spread, let me put it that way, of the results measured.

Q So in the context of pharmacokinetic parameters, what's the difference between a standard deviation and a range of values?

MS. KHANDURI: Objection, form.

A A common practice in the pharmacokinetics area is to report the mean value minus one standard deviation and the mean value plus one standard deviation to give a quantitative or at least a numerical sense of the spread of the results.

Q Is it in general desirable to have a smaller spread in the context of pharmacokinetics?

MS. KHANDURI: Objection, form, foundation.

A In the context of pharmacokinetics, the discipline of pharmacokinetics, what the objective is to obtain and report the numbers without necessarily assigning it a good or bad result is numerical results.

Q All right, I'm going to hand you an exhibit that is pre-marked Exhibit 1022 in this case. Do you have that in hand?

A I do.

Q Do you recognize Exhibit 1022?

A I do.

Q Is that the Bodor reference that you looked at as part of your analysis in this case?

A This is the Bodor reference that I considered.

Q Were you familiar with Dr. Bodor before your work on this case?

A I have known of Dr. Bodor for many years.

Q How did you know of Dr. Bodor for many years?

A He is and has been renowned and really respected pharmaceutical scientist.

Q Have you seen this particular document that is Exhibit 1022 before your work in this case?
A To the best of my recollection, no.
Q And you'll see that there's a co-inventor identified by this document, a Dr. Dandiker. Do you see that?
A I see that.
Q Did you know Dr. Dandiker before your work on this case?
A I did not.
Q So going forward, I'm going to try to alleviate some confusion. When I say "Bodor," I'll talk about the document going forward and not Dr. Bodor the person.
A Understood.
Q And if that gets confusing, please ask me for clarification.
A I will, thank you.
Q So you reviewed Bodor in its entirety as part of your work on this case.
A I did.
Q Did you find any errors in Bodor?

A I cannot point sitting here right now to any specific error on Bodor.

Q So you don't dispute anything that's printed in Bodor.

MS. KHANDURI: Objection, form.

A I do not dispute the information that supports my opinion reported by Bodor.

Q Okay, and so I guess more specifically, you don't dispute any of the bioavailability values reported in Bodor.

A I have no reason to dispute the bioavailability values reported in Bodor.

Q Why don't we take a look at some of Bodor's bioavailability values. Could you please turn to table 6, which is marked as VI in Roman numerals. I know it's a long document.

A I have table 6 in front of me.

Q What is Bodor showing in table 6?

A From the heading of the table, it reads "Ratios of oral to subcutaneous pharmacokinetic parameters and corresponding two-sided 90 percent confidence intervals with cladribine study,"

parentheses, "N equals 12," closed parentheses.

Q And the first column in Bodor's table 6 is headed "Pharmacokinetic Parameter." Do you see that?

A I see it.

Q And in the two rows in that column, I see AUC subscript INF, and then the row below that is AUC subscript T; is that right?

A That is correct.

Q And I think I understand from your declaration that AUC means area under the curve; is that right?

A That is what AUC stands for in pharmacokinetic context.

Q And so looking at Bodor's table 6, what does the subscript INF refer to next to area under the curve?

A It stands for infinity.

Q And what does that mean in this context?

MS. KHANDURI: Objection, form.

A The meaning of infinity or INF subscript in the context of area under the curve in

pharmacokinetics refers to what -- the calculated value for the area under the curve at infinity time in mathematical terms.

Q Then I guess if we look at the row below that, what does the little subscript T mean next to area under the curve?

A It denotes the word "time."

Q And so practically speaking, what does that mean in this context?

A Time in this context is the area under the curve measured when the last measurement was performed in the experiment.

Q In the experiment. When a reader -- when a reader looks at a table like table 6 in Bodor, is there a preference generally between the infinity area under the curve or the time-based area under the curve?

MS. KHANDURI: Objection, form.

A It depends.

Q What does it depend on?

A If the reader wants to have information on what would be the area under the curve once

there is no more drug left in the subject's body, they would refer to the infinity. If the reader is looking to make comparisons at a particular time, then the point times would be the points to consider or compare.

Q In performing your analysis of Bodor, did you rely on the area under the curve at infinity, at time, or both?

MS. KHANDURI: Objection, form.

A I considered Bodor's document in its entirety, so in looking at the parameters reported, I considered them both.

Q So keeping with table 6, the second column going to the right is headed with three milligram tablet 1. Do you see that?

A I see it.

Q And then below that, it's like it breaks this out into two different columns. There's the word "ratio" on the left. Do you see that?

A I see it.

Q And so what does ratio mean in Bodor's table 6?

A Ratio refers to the quotient of two quantities. One of them is the AUC value that was obtained either at infinity or T, and the other refers to the AUC obtained to the subcutaneous AUC.

Q So the -- the values expressed in the ratio column aren't written as one number over another number, right? It's just one number.

MS. KHANDURI: Objection, form.

A The ratio is the result of a division calculation.

Q So is it fair to refer to the number reported in the ratio column as a percentage?

A The values reported under the ratio number are numerically equivalent to a percentage.

Q Okay, so for example, the first number under ratio is 43.1. Do you see that?

A I see it.

Q Is it fair to say that that is a 43.1 percent bioavailability?

A This reports that the area under the curve of the three milligram tablet one is 43.1 percent relative to the area of the curve for the

subcutaneous administration.

Q Can you turn to table 8 of Bodor, which is expressed as VIII in Roman numerals?

A I have table 8 in front of me.

Q And this table also shows in the first column pharmacokinetic parameter. Do you see that?

A I see it.

Q And again, there are two rows, area under the curve infinity and area under the curve time; is that right?

A That is correct.

Q And then to the right, there's a big banner heading over this kind of multitude of columns. It says oral administration. Do you see that?

A I see it.

Q And beneath that towards the left is 3.0 milligrams? Do you see that?

A I see it.

Q And then underneath 3.0 milligrams, the word "ratio" appears again. Do you see that?

A I see it.

Q And would you understand that ratio to correspond to the same ratio we looked at in table 6?

MS. KHANDURI: Objection, form, foundation.

A The type of calculation used to obtain the ratios -- the ratio values reported here on table 8 is the same type of mathematical operation used on table 6.

Q Okay, and for area under the curve infinity in table 8, Bodor reports 34.5 percent for the three milligram tablet; is that correct?

A Bodor reports 34.5 percent for the area under the curve infinity in relation to the area under the curve obtained from the intravenous administration.

Q 43.1 percent is greater than 34.5 percent; is that right?

A Numerically speaking, 43.1 is greater than 34.5. In the context of pharmacokinetic parameters, that is the central value reported. It does not include any ranges.

MR. BERTULLI: I think we've been back about an hour. Should we go ahead and take a quick break?

MS. KHANDURI: Yes, let's take a break.

(Recessed at 11:07 a.m.)

(Reconvened at 11:21 a.m.)

BY MR. BERTULLI:

Q Doctor, welcome back.

A Thank you.

Q You can set aside Bodor. I'd actually like to return to your declaration next. I think you still have that, and when you have that in hand, could you please turn to page 34 of your declaration?

A I have page 34 in front of me.

Q And at the top of page 34, there is a table that you prepared; is that right?

A Correct.

Q And that table summarizes the interpatient variability of prior art cladribine formulations; is that right?

A That is correct.

Q And in this table, you noted that the Albertioni reference reports an interpatient variability of 26 to 27 percent; is that right?

A That is correct.

Q And at the top of the table, you have identified that Bodor reports an interpatient variability of 28 to 30 percent; is that right?

A That is correct.

Q Twenty-six percent is lower than 28 percent, isn't it?

A Numerically speaking, 26 is lower than 28 in percent or in another context.

Q And 27 percent is lower than 28 percent, right?

A Numerically speaking, 27 percent is a smaller value than 28 percent.

Q And as it pertains to interpatient variability, the lower the interpatient variability, the better, right?

MS. KHANDURI: Objection, form.

A Lower interpatient variability is preferable over higher interpatient variability

when administering drugs to patients.

Q Can you turn to paragraph 76 of your declaration and let me know when you're there.

A I have paragraph 76 in front of me.

Q And in paragraph 76, you have written, "And a POSA would have understood that the absolute oral bioavailability of Bodor's tablets and of Stelmasiak's oral solution are at least comparable." Did I read that correctly?

A You did read it correctly.

Q And just so I understand the scope of your opinion here, it is not your testimony that Bodor's bioavailability is increased over Stelmasiak's bioavailability, right?

MS. KHANDURI: Objection, form.

A My opinion is that Bodor's variability and Stelmasiak's bioavailability are at least comparable, taking into account that variability is a range of values. There is a spread. It's not a fixed numerical number.

Q Okay, and -- but you're not saying that one of Bodor or Stelmasiak's bioavailability is

increased over the other's, right?

MS. KHANDURI: Objection, form.

A What I'm opining is that Bodor's bioavailability is at least comparable to the prior art. It could be higher, but it is at least comparable.

Q And it could be lower. Is that true?

A What I refer to when saying at least comparable means that it's at least about the same. Could be higher, but my opinion is that at least they are comparable, meaning similar.

Q So in your next sentence, you've written that the difference between Bodor's range and the prior art and thus Stelmasiak's range is insignificant. Do you see that?

A I see it.

Q So you're not testifying that Bodor's bioavailability is better than Stelmasiak's, are you?

MS. KHANDURI: Objection, form.

A My opinion is that Bodor's bioavailability is at least comparable. It could

be better, but it is at least comparable.

Q It's not enhanced over Stelmasiak's bioavailability, is it?

MS. KHANDURI: Objection, form.

A It is at least comparable. It could be higher, but it is at least comparable. That is my opinion.

Q Do you know one way or the other if Bodor's bioavailability is better than Stelmasiak's bioavailability?

A My analysis has led me to opine that the bioavailability of Bodor's and Stelmasiak's -- Bodor's solid tablets and Stelmasiak's oral solution are at least comparable.

Q Not increased.

MS. KHANDURI: Objection, form.

A The bioavailability of Bodor's tablets and of Stelmasiak's oral solution are at least comparable. That is my opinion.

Q So I appreciate what your opinion is in the paragraph. I want to understand the scope of that opinion and what it includes and what it

doesn't include. So that's why I'm asking, where you write that the bioavailability of Bodor's tablets and Stelmasiak's oral solution are at least comparable, you're not saying that Bodor's bioavailability is enhanced or increased over Stelmasiak's bioavailability.

MS. KHANDURI: Objection, form.

A Can you repeat the question?

Q Of course. What I'm asking is where you write that the bioavailability of Bodor's tablets and Stelmasiak's oral solution are at least comparable, you're not saying that Bodor's bioavailability is enhanced or increase over Stelmasiak's.

MS. KHANDURI: Objection, form.

A What I'm saying is that the bioavailability of Bodor's tablets and Stelmasiak oral solution are at least comparable. Bodor's bioavailability could be higher, but it is at least comparable.

Q If Bodor's bioavailability was higher than Stelmasiak's, wouldn't you have used those

words in paragraph 76?

MS. KHANDURI: Objection, form.

A Can you repeat the question?

Q Sure. I'm using -- I'm looking at the words that you included in paragraph 76 of your declaration, and I need to understand the scope of what that means. In the second sentence that we talked about, you've said that the difference is insignificant. What does insignificant mean?

A Insignificant in the context of comparing bioavailability values means that the spread of the values themselves make them -- the values similar even if they may not be numerically identical because bioavailability, when measured, produces a range of values. There is inherent variability in bioavailability measurements, so the comparison involves looking at the bioavailability as part of the reported values.

Q If one -- if one reference had enhanced bioavailability over a second reference, you wouldn't say that the difference between those two references is insignificant, would you?

MS. KHANDURI: Objection, form.

A That depends on how the definition is applied. The inherent variability between pharmacokinetic measurements of the same formulation on the same group of patients is inherent, and that happens for other studies. So to the extent that they are comparable, the values reported and the spreads, that makes them comparable and therefore, the difference insignificant.

Q But if one set of values was enhanced over another set of bioavailability values, that difference wouldn't be insignificant, would it?

MS. KHANDURI: Objection, form, foundation.

A An enhancement of bioavailability would be such that the spread does not confound the difference.

Q What do you mean -- I'm not sure I understand what you mean by that answer. You said an enhancement of bioavailability would be such that the spread does not confound the difference.

A Bioavailability measurements have inherent variability, so the value of the numerical report of bioavailability is a range, and given that it is a range, when two values are not numerically identical in terms of the center point, so to speak, for lack of a better term, but they have a range that is similar, it can be considered that the bioavailability difference is insignificant.

Q So in your opinion and application of the term, what kind of difference would there need to be between two bioavailability values for you to call one of those values enhanced over the other value?

MS. KHANDURI: Objection, form, foundation.

A In order to make an assessment, the general procedure would be looking at numbers whose difference is not close, taking into account the inherent variability.

Q How would you define not close in your answer?

A If a pharmaceutical scientist or POSA looks at two ranges, because bioavailability, the results are ranges, are not single value, they -- if they -- the single value, which is for shorthand reported, including the range that is given, if those two ranges are similar, then the bioavailability values or ranges are similar, making the difference insignificant.

Q So if you looked at numbers, two different numbers for bioavailability that were not close, does that mean that the difference between those two numbers is not insignificant?

MS. KHANDURI: Objection, form.

A Can you phrase your question without so many negatives?

Q Sure. Well, I was trying to use your words so that we would stay on the same page. So we were talking about numbers, two different bioavailability numbers that are not close. Without using a negative, how would you describe two numbers that are not close?

A Maybe the reporter can help me. I do not

recall having said not close.

Q I asked in your opinion and application of the term, what kind of difference would there need to be between two bioavailability values for you to call one of those values enhanced over the other value. In your answer, you said, "In order to make an assessment, the general procedure would be looking at numbers whose difference is not close."

A Thank you for the clarification.

Q Of course.

A Now let me clarify --

Q Please.

A -- the term "values," at some point after that I mentioned is ranges. I mentioned that a value is sort of like a shorthand notation for bioavailability, but the results are ranges. So if I said value, it was referring to the ranges.

Q Can you identify two examples of bioavailability values where their difference is significant?

MS. KHANDURI: Objection, form, scope.

A In which context? Sorry.

Q Well, so if you look at the bottom of paragraph 76 in your declaration, you've used the word "insignificant" at the end. Do you see that?

A I see it.

Q So what I'd like to understand is when does a difference between the bioavailability of two different references become significant in your mind.

A What -- we can say in the context of cladribine, for example, the prior art reports the values and the ranges of variability. The variability that is reported in the prior art for bioavailability measurements of cladribine has some magnitude. When one experiment provides a numerical reported value and the ranges, that is the same value even if the measurements are not identical because it's part of the same experiment, part of the same type of measurement.

So if we look at the last line on paragraph 76, that reads, "The difference between Bodor's 35.7 to 52.1 percent range and the prior

art," in parentheses, "and thus Stelmasiak's," closed parentheses, "37 to 55 percent range is insignificant." If we look at the reported variability of measurements of bioavailability for cladribine, we will see that the magnitude of those ranges is greater than the differences that we see between these two ranges cited here in my report.

Q So let's unpack some of that answer. So what is a magnitude of a range in this context?

A One frequently used approach is to give a central -- report a central value, plus/minus the standard deviation, for example.

Q So if I have a central value and I have a plus/minus standard deviation, what is the magnitude of that range?

A The central value plus the standard deviation value on the one hand, and on the other hand would be the central value minus the standard deviation, and the subtraction of those two numerical values will give a quantitative measure of the range that is the values as determined for that single experiment.

Q So if I have a central value of ten, are you with me?
A I am.
Q And we have a standard deviation of plus or minus five, you still with me?
A I am.
Q Ten plus five would be 15; is that right?
A That is correct.
Q And ten minus five would be five; is that right?
A Correct.
Q So the range in that case using the standard deviations is five to 15; is that right?
A Correct.
Q So in trying to understand what the magnitude is, is the magnitude ten because that's 15 at the top end minus five at the bottom end?
A That would be in that case the magnitude of the spread of the data within one standard deviation.
Q So I've already lost your earlier answer now, but when you brought up the magnitude of the

spread, how does that magnitude factor into determining whether there's a significant difference between two bioavailability values?

A In simple terms, if when measuring, say, bioavailability in one experiment, one will -- one would obtain a range, there is no difference within one experiment. That is the result. If another experiment shows numbers which are not necessarily identical, but the spread of the values is such that they don't -- they don't fall on different regions, for lack of a better term, there is no information to say that they are different. They're not identical numbers, but if the variation that a scientist has when making a measurement is of the -- of similar or same magnitude as some other -- or some other experiment, there would be no conclusive way of saying that they are different because they fall -- one falls within the range of the other. They don't need to be identical.

Q So in that case where one range falls within the other but is not identical, you'd call that an insignificant difference.

A When the person conducting an experiment mentioning bioavailability, the measurements would be what they are. It's not something that depends on choices of the investigator. It is a result. If the series of numbers that are pertaining to that range are to coincide with experiments -- values from another experiment that had its own range of values, there will be no absolute way or conclusive way of saying that they are different. We can say that they are comparable, and it can be said that the difference is insignificant.

Q In the same scenario that you just described, could you call one set of values or reported value enhanced over the other set?

MS. KHANDURI: Objection, form.

A An enhanced value, the term "enhanced," there's no like formal definition or convention, but what it refers to is to a difference that would have some impact on -- on the performance of the product or some other factors.

Q A difference that would have some impact on the performance of the product would not be an

insignificant difference, right?

MS. KHANDURI: Objection, form.

A That depends.

Q On what?

A It could have -- could be a significant difference or it could not be a significant difference depending on how significant is defined by you and what the specific objective would be on using or not such difference.

Q So you're saying that if there is some impact, that impact may not matter enough to qualify as significant.

MS. KHANDURI: Objection, form.

A It depends on looking at the situation as a whole. In the context of developing a pharmaceutical product, there are multiple considerations taken into account at the same time as a whole.

Q Sure.

A And on those conditions, the difference could or could not be significant depending on what the overall objective for the product at hand is.

Q Can you quantify how many different considerations are taken into account in the context of developing a pharmaceutical product?

MS. KHANDURI: Objection, form.

A I cannot give you a quantitative number as I sit here right now.

Q Is it a lot?

MS. KHANDURI: Objection, form.

A I can say that it is at least more than one.

Q So it's possible that there could just be two considerations taken into account when developing a pharmaceutical product?

MS. KHANDURI: Objection, form.

A I would not put it that way.

Q How would you put it?

A That it is not only one.

Q So when you say not only one, I mean, that's a potential range of two considerations to a million considerations, right?

A I can say that the number of considerations is not a million.

Q Is it a thousand?

A I would say that the number is not a thousand. In my declaration, I list a number of them. It's not necessarily an exclusive list, but it's a number of them.

Q You've said that the list that you've identified in your declaration is not necessarily an exclusive list, correct?

A It's not necessarily exclusive because in terms of dosage forms, there are different types of dosage forms and different routes of administration. So the factors to consider vary depending on the specific situation.

Q And so in the context of your analysis, you didn't look at every single possible factor that is to be considered when developing a pharmaceutical product.

MS. KHANDURI: Objection, form, foundation.

A In forming my opinion for my declaration, I considered those factors that were important for a pharmacologist advising a person of skill in the

art who had decided to utilize cladribine to treat multiple sclerosis as to the type of dosage form to use. The factors that I list are all important ones. When it comes to a dosage form choice, there are some other factors that may be at play, but the ones who help pharmacologists make a recommendation are captured in my declaration.

Q Is developing a pharmaceutical product hard?

MS. KHANDURI: Objection, scope, form.

A I will answer your question based on my experience working on the pharmaceutical industry. It is a process that takes different expertises -- I don't know what the plural of expertise is, but different areas of expertise, and takes time.

Q Is the word "insignificant" a synonym for at least comparable?

MS. KHANDURI: Objection, form.

A In the context of my declaration, the bioavailability of Bodor's tablets and Stelmasiak's oral solution being at least comparable is the result that their difference is insignificant.

Q Is "enhanced" a synonym for at least comparable?

MS. KHANDURI: Objection, form.

A The term "enhanced" aimed in general use in pharmaceutical sciences refers to being greater than, and at least comparable, as I mentioned, it could be, but my view, my opinion is that they are at least comparable, and the choice of enhanced or not all seem too subjective realm. I will limit myself to what I have stated as part of my opinion, that at least comparable means it is at least comparable. Could be higher. If someone chooses to use the word -- a different term for at least comparable, that's beyond my control.

MR. BERTULLI: Why don't we go off the record for one moment.

(Recessed at 12:04 p.m.)

(Reconvened at 12:51 p.m.)

BY MR. BERTULLI:

Q Welcome back.

A Thank you.

Q I am going to hand you an exhibit

pre-marked 2043. Do you have that, sir?

A I do have it.

Q And Exhibit 2043 is a copy of Liliemark from 1992; is that right?

A Correct.

Q And did you look at this exhibit in performing your analysis in this case?

A This exhibit is one of the documents that I considered in forming my opinion for this proceeding.

Q Could you please turn to the page that's marked 1515 at the top, which I think is the second page of the document, and there is a figure 1 at the bottom of the page. Can you please let me know when you're there?

A Sorry, which part? Which paragraph?

Q The figure 1 at the bottom --

A Figure 1.

Q -- of the page.

A I'm looking at figure 1.

Q The caption for -- well, actually, let me step back. Do you understand that capital C lower

case D capital A means cladribine?

A Yes, that is my understanding.

Q Okay, so then if I go back to figure 1, the caption reads, "The plasma concentration of cladribine after IV, SC and oral administration in patient number 7." Do you see that?

A I see it.

Q Okay, and then if we look to the figure, the X axis is labeled time H. Do you see that?

A I do.

Q So what do you understand the X axis in figure 1 to show?

A It corresponds to the time measured in hours starting with the administration of the drug to a patient and followed over a period of 72 hours.

Q And the Y axis of figure 1 is labeled "Concentration of Cladribine in Plasma." Do you see that?

A I see it.

Q And then I think it's got a unit that's a little N capital M. Is that nanomolars?

A In my understanding, that is nanomolar.

Q Okay, so what is the concentration of cladribine in plasma generally?

MS. KHANDURI: Objection, scope.

BY MR. BERTULLI:

Q What does it mean?

MS. KHANDURI: Objection, form.

A Well, the concentration of cladribine in plasma is the concentration that is solution in the plasma.

Q In a patient's plasma?

A Specifically from these figures, it's on patient number 7.

Q Okay. On the Y axis, there are three numbers going from the bottom, 10, 100 and 1,000. Do you see those?

A I see it.

Q So can you quantify what the difference is between a hundred nanomolars and a thousand nanomolars?

MS. KHANDURI: Objection, form, foundation.

A A hundred nanomolar is one tenth of a thousand nanomolar.

Q And so does the same follow that ten nanomolars is one tenth of 100 nanomolars?

A Ten nanomolars is one tenth of 100 nanomolar.

Q Okay. You can put that exhibit aside. I'm now handing you an exhibit marked 1018.

MS. KHANDURI: Thank you.

BY MR. BERTULLI:

Q And do you have that one in hand?

A I do.

Q And this is a paper by Rice; is that correct?

A That is correct.

Q And did you analyze Rice as part of your work in this case?

A This exhibit is one of the documents I considered in forming my opinion for these proceedings.

Q Okay, so if you keep Rice, I'd like to ask you a question about your declaration, if you

could sort of keep Rice at hand and then turn to paragraph 82 of your declaration please.

A I have paragraph 82 of my declaration in front of me.

Q Okay, and the -- the second half of this -- well, actually, I'll read the whole second sentence of paragraph 82. You write, "And because Rice's 0.7 milligram over kilogram dose caused a lymphocyte suppression, a POSA would have reasonably expected Bodor's 0.6 to 0.8 milligram over kilogram dose also to suppress lymphocytes to a similar level as Rice's dose." Did I read that correctly?

A You did.

Q So with that in mind, if you could please turn in Rice to figure 4, which is at the top of Rice's page 8, and please let me know when you're there.

A I have figure 4 of Rice's paper in front of me.

Q Okay, and is it right that figure 4 in Rice shows three different profiles, one for a

placebo, one for cladribine at 0.7 milligrams over kilograms, and one for cladribine at 2.1 milligrams over kilograms?

MS. KHANDURI: Objection, form.

A Figure 4 in Rice's paper shows a graph with three sets of data in a plotted form. One corresponds to a placebo, another one to cladribine 0.7 milligrams per kilogram, and another one corresponds to cladribine 2.1 milligrams per kilogram.

Q And the set of data that corresponds to the placebo appears to be indicated by little plus signs in Rice's figure 4; is that right?

A That is what I see in the block.

Q And the set of data corresponding to cladribine at 0.7 milligrams per kilogram appears to be identified as open circles in Rice's figure 4; is that right?

A That is what I see in figure 4.

Q So when you said in paragraph 82 of your declaration similar to Rice's dose, are you referring to the set of data in figure 4 that's

indicated by open circles?

A The 0.7 milligrams per kilogram reported in Rice correspond to the cumulative dose of cladribine administered to the patients, and that is the value that I'm referring to in my declaration.

Q You can put Rice aside, and in your declaration -- actually, we get to stay in the same place. So page 43 still, I'll give you a moment to organize your papers.

A Forty-three of my declaration?

Q Yeah.

A I am on page 43 --

Q Okay.

A -- of my declaration.

Q In -- there are two calculations that you've shown for equivalent subcutaneous dose right above paragraph 82. Do you see that?

A I see it.

Q What does the word "equivalent" mean in those equations in your declaration?

A I will refer you to paragraph 80, where

it -- I'm going to read the first sentence is, "As explained, Bodor teaches administering," open quotes, "ten milligrams of cladribine," ellipsis, "and once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment," and then it says Exhibit 1022, 23:15-20. Exhibit 1022 is a document that you handed to me earlier today, and this is Bodor's paper.

So we go to page 23, line 15, it states, "At the present time, it is envisioned that for the treatment of multiple sclerosis, ten milligrams of cladribine in the instant complex, cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment."

If we look at Bodor's teaching regarding the cyclodextrin-cladribine complex in the --

cladribine-cyclodextrin complex in the solid dosage form, and then the doses and times taught in Bodor is ten milligrams of cladribine in the instant complex, as I said, and then it's for a period of five to seven days.

So the product of ten times five or ten times seven leads us to the numbers that are being used in the calculations just above page 82, which is the cumulative dose utilizing Bodor's complex formulation in the solid tablet using Bodor's regimen in terms of time. The 1.4 and 2.0 that appear in the two calculations are obtained in that way.

The next element in this calculation is a multiplication times 0.4. That we can see starting on paragraph 81 of my declaration says, "A POSA as advised by a pharmacologist would have understood that Bodor's oral dose corrected for its bioavailability," parentheses, about 40 percent, closed paren, comma, "is the dose," parentheses, "in milligrams per kilogram," closed parentheses, "times 0.4," parentheses, "i.e., 40 percent

bioavailability."

So the parameter 0.4 corresponds to the approximate value of the bioavailability of Bodor's formulation in Bodor's oral solid tablet following Bodor's regimen, rounding it up to 40 percent for ease of calculation. So the product 1.4 times 0.4, the result is 0.56 milligrams per kilogram, and the product of 2.0 times 0.4 is 0.8 milligrams per kilogram.

Q So my question was what does the word "equivalent" mean as you used it here. Did -- was that your answer?

A It was part of my answer. I forget the second part of your question, so --

Q Okay.

A Let me complete the answer. The bioavailability of Bodor's formulation and Bodor's dosage form is about 40 percent. So the numbers that are represented here is the -- respond to the values of dose that would be given to a patient if all of the drug was completely bioavailable. So it is the correction that is needed so that -- to

account for the fact that not all of the drug in a dosage form -- the oral dose formulation in Bodor's tablet given orally goes into the blood.

Q So using your understanding of the word "equivalent," is it right that equivalent doses would have a similar concentration of cladribine in the plasma when administered?

A In the simplest way of putting it is if this -- if the drug is administered into the bloodstream, 100 percent of the drug goes into the bloodstream because the investigator placed it there. In the -- from relation to Bodor and solid tablets, not 100 percent of the drug makes it into the blood because the bioavailability is 40 percent. So the amount of drug that would reach the systemic circulation utilizing Bodor's formulation, Bodor's oral tablets and Bodor's regimen for treatment would be equivalent to administering the amounts of drug reported here as a result of the calculations if they were administered intravenously, and from the prior art, it has been found that the bioavailability of the

subcutaneous route is very much the same as intravenous. So this is point 556 and point 8 would be what would be the equivalent amount of dose that would be needed in order -- correcting for the fact that Bodor's formulation, solid formulation is a solid tablet, to make it equivalent to giving it either an intravenous or subcutaneous administration.

Q Okay, thank you for that answer. So earlier, before our break, we had discussed your opinion that the difference between Bodor's bioavailability and Stelmasiak's bioavailability is insignificant. Do you remember that?

A Yes, I do.

Q Okay, so does that mean that 100 milligrams of cladribine dosed under Bodor's formulation and 100 milligrams of cladribine dosed under Stelmasiak's formulation would be equivalent?

MS. KHANDURI: Objection, form.

A I don't think I understand your question.

Q Well, we covered earlier that the difference in bioavailability between Bodor and

Stelmasiak is insignificant. You remember that?

A We talked about the difference between the ranges that we -- I have -- I report here on the last sentence for paragraph 76, we discussed about the ranges, of the magnitudes of the ranges, as well as the variability. Another aspect that is relevant here is that in the case of Stelmasiak's results, there is no wash-out period, so that the numbers are somewhat over-inflated, so they will be slightly lower, making them closer, and reporting what it's -- on the prior art, but it would take into account that there's no wash-out period in Stelmasiak's reported values, brings it even closer, but even with that, the range -- the difference in ranges is insignificant.

Q So if the difference in bioavailability between Bodor and Stelmasiak is insignificant, does that mean that a hundred milligram dose of Bodor and a hundred milligram dose of Stelmasiak are equivalent as you used the word "equivalent" on page 43 of your declaration?

A The word "equivalent" as used in the

calculations in page -- I'm sorry, in -- on paragraph 81 refers to the exercise in which if an amount of drug is going to be administered via injection versus having an amount of drug administered utilizing Bodor's formulation in Bodor's solid tablet dosage form and Bodor's regimen -- regimen of dose, what would be the amount of drug given in Bodor's formulation to be equivalent in terms of amount of drug making it into the blood. So that is what the equivalence refers in to that.

So your question was about the pharmaceutical equivalent, but I'm not sure I follow your question.

Q Well, so if -- and I apologize for all the sirens that are going on outside. I didn't -- I didn't do that. If Bodor and Stelmasiak have an insignificant difference in their bioavailabilities, then does that mean that a 10 milligram dose of Bodor and a 100 milligram dose of Stelmasiak would result in the same cladribine concentration in the patient's plasma?

MS. KHANDURI: Objection, form.

A Considering the difference in bioavailability between Bodor's formulation and solid dosage form is insignificant to the bioavailability of Stelmasiak's oral solution, what my opinion is is that the -- giving a particular amount of the drug would make Bodor's bioavailability at least comparable to Stelmasiak's reported values.

Q So for a given amount of drug, your testimony is that Bodor's bioavailability will be at least comparable to Stelmasiak's bioavailability.

MS. KHANDURI: Objection, form, foundation.

A For a given amount of drug of cladribine administered to a patient, the bioavailability of Bodor formulation and solid oral tablet would be at least comparable to the bioavailability of an oral solution containing the same dose of drug.

Q Does it then follow that the administration of each of Bodor on the one hand and

Stelmasiak on the other hand in the same amount of the drug would result in the same plasma concentration of cladribine?

A With everything else equal, the same amount of drug given -- utilizing Bodor's formulation and Bodor's solid dosage form, the bioavailability will be at least comparable to that of administering the same amount of drug utilizing Stelmasiak's oral solution.

Q And so how would that affect the plasma concentration of the cladribine?

MS. KHANDURI: Objection, form.

A With everything else equal, giving the same dose with comparable bioavailability, the areas under the curve would be expected to be comparable.

Q Let's -- I have another exhibit to share. I am going to hand you an exhibit that is already marked 1013. Do you have that exhibit, 1013, in hand, Doctor?

A I have it with me.

Q And is that a copy of the Stelmasiak

reference that we've been talking about a little bit this afternoon?

A This is the copy -- this is a copy of the Stelmasiak reference we have been talking about.

Q And you studied Stelmasiak in its entirety as part of your analysis in this case.

A I read Stelmasiak in its entirety as part of forming my opinion for this proceeding.

Q Had you ever seen this paper that we're calling Stelmasiak before your work in this case?

A To the best of my recollection, no.

Q Were you aware of Stelmasiak, scientist, before your work in this case?

A I was not.

Q And I guess just for a moment, earlier, we had been talking about the Rice paper. Do you remember that?

A I do remember.

Q Had you ever encountered the Rice paper before your work in this case?

A I don't believe I have.

Q And have you ever encountered Rice, the

scientist, before your work in this case?

A I have not.

Q One more pair of questions like that. We talked about Liliemark earlier. Do you remember that?

A I do remember.

Q Okay, and had you ever encountered that Liliemark paper from 1992 before your work in this case?

A I don't believe so.

Q And had you ever encountered Liliemark, the scientist, before your work on this case?

A I have not.

Q Okay. So turning back to Stelmasiak, can you please show me where in Stelmasiak the bioavailability range of 37 to 55 percent is reported?

A Stelmasiak did not measure bioavailability. What Stelmasiak does is to cite to Liliemark, and that citation is found on page 2 of Exhibit 1013 on the right-hand side on the ninth line under reference number 12. If we go in the

Stelmasiak to page 5, we find the references cited by Stelmasiak, and under number 12, we have the Liliemark paper, which is the paper we -- you handed to me, which is Exhibit 2043.

Q Okay, so the range 37 to 55 percent isn't shown expressly in Stelmasiak.

MS. KHANDURI: Objection, form.

A Well, Stelmasiak is explicit on its citations, so I wouldn't put it the way you do because even though the characters -- you know, the actual text or numbers or -- you know, are not typed in Stelmasiak's paper, Stelmasiak provides a reference, and that reference has the values.

Q Okay, and when you say that reference has the values, you mean Liliemark 1992, which is Exhibit 2043?

A It is Stelmasiak's Exhibit 2043.

Q Can you please show me where Liliemark discloses a bioavailability range of 37 to 55 percent?

A If you look at the sentence -- the last sentence on paragraph 76 where it says the

difference between Bodor's 35.7 to 52.1 percent range and the prior art, and those Stelmasiak's, in parentheses, 37 to 55 percent range is insignificant. Now, this sentence is referring to the prior art, which includes Stelmasiak's. Now, if we look at paragraph 75, and actually, my declaration, the 37 to 51 percent, the range that appears there, this is from -- I don't know the number, but there is Liliemark's paper published in 1997, and this number -- this range is captured in that publication.

Now, if you go to the Liliemark 1992, which is 2043, and if you go under results, on page 1515, on the seventh line, that shows the 55 percent, which is part of the prior art. So what I put is Stelmasiak's in parentheses, I'm making reference to the prior art. So the prior art in one reference includes 37 to 51, in another reference, includes 55, and that covers the range that has been reported in the prior art.

Q Could you go to the portion of the results in Liliemark 1992 that you just directed me

to?

A I have it in front of me.

Q And I see written here, the bioavailability was 55 percent plus or minus 17 percent. Do you see that?

A I see it.

Q And you selected 55 percent here for your range; is that right?

A That is the number that I used in the range that I wrote.

Q So why did you stop at 55 percent and not count up another plus 17 percent to 72?

A The general practice in the pharmaceutical field is -- when making comparisons of this sort, is to give the reported values as the central value, for lack of a better term, so that to make a simple statement. It is common sense for a pharmaceutical scientist to realize immediately that the numbers are not fixed numbers, but that the numbers reflect a representative value that invariably comes along with a range.

So for purposes of making general

comparisons, utilizing the representative number is common practice, and that's what I did in this particular case.

Q Well, if you turn back to Liliemark 1997, which you have a snippet of in paragraph 75 of your declaration -- yeah, it's right in your declaration on paragraph 75.

A Oh, yes.

Q So Liliemark 1997 discloses a range that varies from 37 to 51 percent. Do you see that?

A I see it.

Q So you used the range of 37 to 51 percent from Liliemark '97 and not a representative value when you analyzed that reference.

MS. KHANDURI: Objection, form, foundation.

A I'm totally lost on that one.

Q Well, sure, so we'll go through it again. So look at your snippet in your paragraph 75.

A Okay.

Q And 37 to 51 percent is disclosed in Liliemark '97. You agree?

A That is a fact, these are the numbers reported in Liliemark's 1997.

Q Thirty-seven to 51 is a range. Is that true?

A It is -- the way to read this, and the way a pharmaceutical scientist will understand is that 37 is a representative value which has a range, and 51 is a representative value which also has a range. So what a review paper or like this, similar to what I did on the last sentence of paragraph -- yeah, of paragraph 76 is to report on the representative values. It is very important not to get confused into the 37 to 51 percent as reported by Liliemark 1997 correspond to some undisclosed representative value, and that the range is 37 to 51.

I don't know in how many ways I need to say it to make this extremely clear. Thirty-seven to 51 percent is not the range. It is the representative values of two ranges, one lower, one higher.

Q Let's turn to page 37 of your

declaration, and you have a table up at the top. Do you see the row where you have Liliemark 1992?

A I see it.

Q And then under bioavailability, you have written 48, comma, 55 percent. Do you see that?

A I see it.

Q Are those 48 and 55 percent two representative values from Liliemark '92?

MS. KHANDURI: Objection, form.

A Okay, it is important to clarify what I mean when we say representative value.

Q Uh-huh.

A Representative value is shorthand. Every measure of bioavailability includes a set of numbers. That set of numbers has a range, and for shorthand, a value which is -- which I'm calling representative here is what is used -- instead of giving 48 plus/minus whatever, or 55 plus/minus whatever, is -- and I would change the terms so that we don't get into miscommunication. Instead of saying representative value, I can say it's something like a summary value or a single value to

use for communication or shorthand value. We can use different terms, not to be understood that representative has some particular weight. It's just -- it's impossible to get bioavailability as a single value. It just doesn't happen, but it's often reported as a single value. Whatever we decide to call that value, and I would be happy to -- for us to find a term that represents that, that is what is meant when I say representative.

Q You just proposed the term "summary value" for the purposes of this discussion. Would you be comfortable using the term "summary value"?

A I took that term on the flight -- on the fly as I'm speaking right now here. If we agree that summary value or whatever value is the one number that is used to guide people reading this type of information, that is -- that is something that I can agree on. What I cannot agree on is in trying to attribute other meanings to the terms.

Q And I'm not trying to do that. I'm just trying to understand the variety of numbers that you've collected in your declaration and where they

come from. So at the top of page 37, for Liliemark 1992, you've identified 48 percent, comma, 55 percent. Do you see that?

A I see it.

Q Can we describe 48 and 55 percent as summary values for Liliemark 1992?

A In the context of what specific measurements Liliemark is referring to, we can use that terminology for brevity of time.

Q Okay, then let's go back to page 40 of your declaration, paragraph 75. The snippet that you got here from Liliemark 1997, do you see where it says 37 to 51 percent?

A I see it.

Q Is it your understanding that Liliemark '97 is trying to express that 37 percent is one summary value, and 51 percent is another summary value?

A In the context of this publication, which is a review of the prior art, that Liliemark look at different prior art publications, and reports on what are the ranges.

Q It's a range, sir, right?
A A range is ranges, so we are getting into this difficulty because this is the range of summary values, but each summary value has its own range. So 37 is 37 plus/minus something, and 51 is 51 plus/minus something, but the purpose of this type of publication, which is a review, serves no purpose to extend the amount of text and characters. The purpose is to provide the information, which is 37 as a representative -- sorry, as a summary value, and 51 as a summary value, not as precise values measured, because a precise value is not measured.
Q So now, where Liliemark 1997 says 37 to 51 percent, I'm to understand that in Liliemark '97, 37 to 51 percent is a range of ranges of bioavailability?
MS. KHANDURI: Objection, form.
A If we want to get into what those numbers are --
Q I do.
A And I'm using it to explain what it is.

The 37 percent reported is a value that captures values reported in the literature, and there's no measurement of bioavailability that gives a single value. So that captures what is the -- the magnitude that could be obtained on one side, and the 51 percent similarly, it captures, reports the order of magnitude that would be expected on the other side.

Q So let's just flip back to page 37 in your declaration up at the table at the top. So for Liliemark '92 where you've written 84 comma 55 percent, should you have written -- excuse me, 48 to 55 percent --

MS. KHANDURI: Objection.

BY MR. BERTULLI:

Q -- for Liliemark '92?

MS. KHANDURI: Objection, form, foundation.

A What I have written here are values which were presented in the publication, and approximately 50 percent is also something that is on the prior art, so I'm reporting on that, so I

should have done what I did, which I reported 48 and 55.

Q So let's start with the 48 percent for Liliemark '92. Is 48 percent a summary value?

A I am going to refer you to Liliemark 1992, and if we look -- it doesn't have a header, but the abstract on the first page on the right-hand side column, on the fifth line, you can read that it says the bioavailability was 48 percent plus/minus eight percent. So going back to your question, Liliemark is reporting 48 percent plus/minus eight percent. Now, for the purposes of today's -- today's exchange between you and me, we have agreed that the 48 percent is what we would call a representative value -- or sorry, a summary value.

So the value that is being reported as the summary, so to speak, is 48, but the range is not 48. It's not a single point, and the sides of the ranges with the plus and negative sign gives the -- the extent of the range to the left and to the right.

Q So looking at the table on page 37 of your declaration, should I understand that for Albertioni, the values of 42 and 46 percent are summary values of bioavailability?

A What I have done in putting together this table is what it is typically done in the field, to report what we have agreed to referred to as summary value in these numbers. So I did the same type of consideration and value reported in the table, in the other values for Albertioni.

Q Okay, let's turn back to paragraph 76 of your declaration.

A I have it in front of me.

Q So am I right then that where you write 37 to 55 percent at the bottom of that paragraph, 37 to 55 percent is comprised of a range of summary values collected from the prior art?

MS. KHANDURI: Objection, form, foundation.

A What I will say is that the numbers that we see, 37 and 55, would correspond to the single summary value that would be used in communications

of this sort, so I'm applying that type of approach.

Q I think I understand, but the way that you've written this, it says 37 to 55 percent range. Do you see that? So --

A I see it.

Q So what I'm trying to understand, if the 37 to 55 percent range is a range of summary values.

A In the context of this type of information, when a single value is reported, it is necessarily a summary value because it is not possible to experiment and measure a single value.

Q Now looking at the same sentence, is it your testimony that Bodor's reported range of 35.7 to 52.1 percent bioavailability is also a range of summary values?

MS. KHANDURI: Objection, form.

A In the context of measuring bioavailability, when a single value is reported, it's just as a summary value because as I said, it is not possible to get a single value when

measuring bioavailability.

Q Do you still have your copy of Bodor?

A I do.

Q Could you please grab that and turn to table 6, and just please let me know when you're there.

A I have table 6 in front of me.

Q So if you look under the three milligram tablet one column, are you there?

A I am there.

Q And then you'll see there's a column to the right that says LL comma UL? Do you see that?

A I see it.

Q Does that mean lower limit, upper limit?

A That is what my understanding is.

Q And then the two numbers right below that are 35.7 and 52.1. Do you see those?

A I see it.

Q And those numbers correspond with the range that you have identified as Bodor's range in paragraph 76 of your declaration; is that right?

A That is correct.

Q But right to the left of those two numbers in Bodor's table 6, Bodor reports 53.1 percent, like we talked about earlier. Do you see that?

A Are we on page 6? I mean, sorry, what --

Q I'm sorry, I must have misspoke. Let me try that again. To the -- to the left of those two numbers in Bodor's table 6, Bodor reports 43.1 percent that we talked about earlier. Do you see that?

A That is the ratio.

Q Is that the summary value?

A That would be the ratio of what is considered the summary value because a division needs to be made, and then it needs to have two numbers, so one needs to be taken -- a single number needs to go into the numerator -- into the numerator, and a single number needs to go into the denominator.

Q All right, and since there's one number reported here, 43.1, that is Bodor's summary value.

MS. KHANDURI: Objection, form,

foundation.

A That would be a number that is calculated utilizing the summary value, which is the practice in the field.

Q What summary value would have calculated that 43.1?

MS. KHANDURI: Objection, form.

A When there is a range of values, and the investigator needs to use one number, would be to find one that, for lack of a better term, summarizes the information, that is the value that is typically used.

Q Is -- is it your testimony that 43.1 does not summarize the information for Bodor's three milligram tablet?

MS. KHANDURI: Objection, form.

A One thing. When you say summarize, are you connecting it to whether there's physically unique meaning of the word "summary" that we're using right now, or what I need you to clarify.

Q Well, sir, so your answer to me on my last question was the investigator needs to use one

number, would be to find one that, for lack of a better term, summarizes the information, that value is typically used. So I guess what I'm trying to understand is how does the 43.1 relate to what we've been talking about as summary values this afternoon.

A The way that number, 43.1, was obtained in this type of studies is as follows. Patients are administered the drug, and the concentrations in plasma are measured, and from those measured numbers, areas under the curves can be constructed. Those areas under the curve correspond -- there are as many as patients in the study. In order to capture one value that is representative or a summary or whichever way we want to say it, but it's a single value, that is taking a summary value.

The same is done for the other route of administration, which in table 6 of Bodor is the subcutaneous administration, and again, there will be as many areas under the curve or as many curves, each one with area as patients, so from that, the

number are summarized into some value to utilize, and those two summary values are divided one by the other, and that's what leads to the values reported here, so that is how these type of values are obtained.

Q So I want to make sure I understand. Does that mean that one summary value was divided by another summary value to arrive at the 43.1 percent that's reported by Bodor?

A The value of 43.1 is the result of dividing one number by another, and those two numbers that are being divided are obtained from a set of numbers that were experimentally determined. So if we adopt the word "summary value" for the number that was adopted from that set, that is how this -- this 43.1 number was obtained.

Q Is the 35.7 number a summary value?

A The 35.7 value is the lower value that was obtained within the variation of the lower end. There is always variability among patients, and even among measurements. So in general, in scientific publications, when experiments are

performed, the numbers always have some variation, and the number, summary value, is what is used when one single number is going to be utilized in further calculations or analysis.

Q So the 35.7 reported here is not a summary value then.

A It is the value within the inherent variability that was determined as the lower value within the range.

Q Is it a summary value as we've been using the term today?

MS. KHANDURI: Objection, form.

A It is a value that captures the lower measurement without the need to specify variation to that.

Q Does that mean it's a summary value?

A The summary value is used for reflecting the general range, as I mentioned for bioavailability. This 35.7 to 52.1 represent the low and high ends of that range.

Q So they are not the summary values.

MS. KHANDURI: Objection, form.

THE WITNESS: The summary values --
MS. KHANDURI: Foundation.
THE WITNESS: -- of what?
BY MR. BERTULLI:
Q You said, "The summary value is used for reflecting the general range. This 35.7 to 52.1 represent the low and high ends of that range."
MS. KHANDURI: Objection, form, foundation.
THE WITNESS: Those are the represent -- well, let me put it this way. The 35.7 and 52.1 are the summary values of the low end and high end of the range.
MS. KHANDURI: Counsel, can we take a break? We've been going for about an hour.
MR. BERTULLI: Yeah, let's take a break.
(Recessed at 2:03 p.m.)
(Reconvened at 2:19 p.m.)
BY MR. BERTULLI:
Q Doctor, welcome back.
A Thank you.
Q Could you please pick up the copy of Rice

that I gave you a little earlier?

MS. KHANDURI: It's on the other side.

THE WITNESS: Oh, okay.

MS. KHANDURI: Thanks.

THE WITNESS: Oh, got it. I put it back. I have it in front of me.

BY MR. BERTULLI:

Q Okay, excellent, and could you please turn to figure 4 of Rice that we looked at a little earlier?

A I have figure 4 in front of me.

Q And then if you still have your declaration handy, can you turn to paragraph 80?

A I have paragraph 80 in front of me.

Q And towards the end of that paragraph, you wrote, "And as I understand that Dr. Miller further explained, and I agree, Bodor's induction dose was 100 milligrams to 140 milligrams." Did I read that correctly?

A You.

Q And then the next sentence reads, "For an average weight patient, the induction dose equals

1.4 to 2 milligrams per kilogram," and then in parentheses, it says a hundred milligrams or 140 milligrams, divided by 70 kilograms. Do you see that?

A I do.

Q And the 70 kilograms is the patient's weight; is that right?

A Seventy kilograms in the pharmaceutical field is used as the average weight of a patient, so this is basically the number that is used when an average patient needs to be put into consideration, that is the number that the entire field uses.

Q Got it. So then looking at figure 4 of Rice, is it your opinion that if Bodor's 100 to 140 milligram dose is given to a patient having a 60 kilogram average weight, then the lymphocyte profile of the patient will be similar to Rice's figure 4 profile for 0.7 milligrams per kilogram?

MS. KHANDURI: Objection, form, foundation, scope.

A Your question doesn't make sense.

Q Why not?

A If I heard you correctly, you referred to a patient with an average weight of 60 kilograms. The average weight of the same patient is his weight.

Q Yeah, I was hoping that that was a typo, but I actually misspoke, but I'll try again.

A Okay.

Q So is it your opinion that if Bodor's 100 to 140 milligram dose is given to a patient having the 70 kilogram average weight, then the lymphocyte profile will be similar to Rice's figure 4 for the 0.7 milligram per kilogram profile?

MS. KHANDURI: Objection, form, foundation, scope.

A My opinion is not based on a patient with a weight of 70 kilograms. My opinion is directed to the dose that would be given to an average patient, which is a hypothetical situation, and the number that I use is 70 kilograms because that is the number that is used in the pharmaceutical field, and my opinion is that for an average

patient, giving the solid complex -- sorry, the solid complex cyclodextrin-cladribine form of the drug in the formulation of solid oral dosage tablets following the regimen described by Bodor, the dose that would be given to that average patient, the cumulative dose would be of the same order of magnitude as the point 7 that we see in figure 4, point 7 milligrams per kilogram we see in figure 4 of Rice, and my opinion is that if the dose that is being given to the average patient is of similar magnitude as the dose reported in Rice, there would be an expectation that the pharmacological effect would be similar.

Q When you say that the pharmacological effect would be similar, does that mean that it would suppress lymphocytes to a similar level?

A In the context of my declaration, the pharmacological effect corresponds to lymphocyte suppression.

Q Okay, can you please now -- you can set Rice aside. Can you please turn back to paragraph 76 of your declaration?

A I have paragraph 76 of my declaration in front of me.

Q Okay, so you see where you've written Bodor's 35.7 to 52.1 percent range?

A I see it.

Q And 35.7 corresponds to the lower limit that was reported in Bodor; is that right?

A From the numbers in table 6, 35.7 corresponds to the lower limit.

Q And the 52.1 percent corresponds to the upper limit reported in Bodor's table; is that correct?

A 52.1 percent corresponds to the upper limit reported on table 6 of Bodor's document.

Q And then later on in the same sentence from paragraph 76, you've got a 37 to 55 percent range for the prior art; is that right?

A Those are the numbers that I write for the range of the prior art.

Q Okay, and then do you have your copy of Liliemark from 1992 handy? I'll hold up mine to help you figure out which one's which.

A Yes, I have it in front of me.

Q Okay, and then under results on the cover of Liliemark, about seven lines down, Liliemark writes, "The bioavailability was 55 percent plus/minus 17 percent," right?

A Correct.

Q Okay. Fifty-five minus 17 percent is 38 percent; is that right?

A I would say yes.

Q And 55 percent plus 17 percent is 72 percent; is that right?

A That calculation will be correct.

Q Okay, and then do you still have your copy of Stelmasiak handy?

A I do.

Q Could you please turn to the references section that we talked about a little earlier?

A I have the reference section of Stelmasiak in front of me.

Q And we talked about how at reference 12, Stelmasiak had cited to the Liliemark 1992 paper. Do you remember that?

A I do.
Q Stelmasiak does not cite to Saven, does it?
A Can you specify which specific reference by Saven you refer to?
Q Yes, if you turn to page 10 of your declaration --
A Okay, I have it in front of me.
Q This is the table of exhibits that you considered in forming your opinions; is that right?
A It is.
Q Okay, and I think the third one up from the bottom, Exhibit 1074 is Saven?
A I see it.
Q And there's the Exhibit 1074 is the Saven you referred to in your declaration, right?
A The 1074 exhibit is the Saven I referred to in my declaration.
Q Okay, and does Stelmasiak cite the Saven that you refer to in your declaration?
A Stelmasiak cites Saven, but not this specific publication.

Q Okay, and when you say that, you're referring to reference 6 in Stelmasiak?

A Yes, if I recall correctly, you mentioned in your question that Stelmasiak does not cite to Saven, which is not the case. He does.

Q Sure.

A But it's a different publication by Saven.

Q Right, and so it's a good point of clarification. So the Saven that is Exhibit 1074 that you relied on in this case is not cited by Stelmasiak.

A It is not.

Q And Albertioni is not cited by Stelmasiak, is it?

A Albertioni is not cited by Stelmasiak.

Q And Liliemark 1997 that we talked about earlier is not cited by Stelmasiak, is it?

A Liliemark 1997 is not cited by Stelmasiak.

Q And Doctor, just to confirm the scope of your expertise, you do not have an M.D.; is that

right?

A I do not have an M.D.

Q Have you ever yourself treated a patient?

A My work has not involved treating patients directly.

Q Have you yourself ever diagnosed a patient with a disease?

A I have not diagnosed patients with a disease.

Q Do you have any specific education or training with regard to multiple sclerosis?

A I have no specialized training on multiple sclerosis.

Q Besides your work on this case, have you ever done any work with cladribine?

A My previous work has not involved cladribine.

Q Have you ever advised a physician or medical doctor regarding the treatment of multiple sclerosis?

A I have not.

Q And during the course of your deposition

today, did you at any time speak with counsel regarding the substance of your testimony?

A I did not.

MR. BERTULLI: Thank you so much for your time, Doctor. We have no further questions pending any redirect.

THE WITNESS: Thank you.

MS. KHANDURI: Let's take a 15-minute break.

(Recessed at 2:37 p.m.)

(Reconvened at 2:53 p.m.)

EXAMINATION BY COUNSEL FOR HOPEWELL PHARMA VENTURES, INC.

BY MS. KHANDURI:

Q We have a short redirect. Dr. Pinal, throughout the day today, opposing counsel has presented you with various papers and has asked you various questions, including asking you to perform various analysis. Do you recall that?

A I have a general recollection.

Q To what extent, if any, do these papers, questions and analyses impact your opinion as set

forth in your declaration?

A My opinion has not changed.

MS. KHANDURI: Thank you. We pass the witness.

MR. BERTULLI: We're all set. Thank you.

(Off the record at 2:54 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, Rodolfo Pinal, 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)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, KAREN YOUNG, Court Reporter and Notary Public within and for the District of Columbia, do hereby certify:

That Rodolfo Pinal, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition, and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, Hopewell Pharma Ventures, Inc., was represented by counsel at the deposition.

I further certify that the deposition of Rodolfo Pinal, Ph.D. occurred at the offices of Sterne, Kessler, Goldstein & Fox PLLC, 1101 K Street, Northwest, Washington, D.C., on Friday, April 26, 2024, commencing at 9:03 a.m. to 2:54 p.m.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to

any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 30th day of April, 2024.



NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

My commission expires:
July 31, 2024

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