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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
IPR2023-00481

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4
5 HOPEWELL PHARMA VENTURES, INC.

6 Petitioner,

7 v.

8 MERCK SERONO S.A.,

9 Patent Owner.

10
11
12 IPR2023-00480
13 U.S. Patent 7,713,947
14 IPR2023-00481
U.S. Patent 8,377,903

15 Deposition of RODOLFO PINAL, PH.D.

16 Washington, D.C.

17 Friday, April 26, 2024

18 9:03 a.m.

19
20 Job No. 534629

21 Pages 1 - 134

22 Reported by: Karen Young

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

3 STERNE, KESSLER,
4 GOLDSTEIN & FOX, P.L.L.C.
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6 Washington, D.C. 20005
7 (202) 371-2600

8
9
10
11
12 Pursuant to notice, before Karen Young,
13 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

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C O N T E N T S

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By Ms. Khanduri.....	130

EXHIBITS REFERRED TO

(Retained by Counsel)

Exhibit 1013	Paper by Stelmasiak et al.....	98
Exhibit 1018	Paper by Rice et al.....	86
Exhibit 1022	World Intellectual Property Organization Publication No. WO 2004/087101 A2.....	53
Exhibit 1080	Declaration in IPR2023-00480...	6
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1 (Exhibits were marked prior to the deposition.)

2 P R O C E E D I N G S

3 RODOLFO PINAL, PH.D.,

4 having been duly sworn, was examined as follows:

5 - - -

6 EXAMINATION BY COUNSEL FOR MERCK SERONO S.A.

7 BY MR. BERTULLI:

8 Q Good morning, Dr. Pinal.

9 A Good morning.

10 Q Thank you for joining us today.

11 A Thank you.

12 Q You understand that you're under oath
13 today?

14 A I do.

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

17 A There is no reason.

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

21 A That is my understanding.

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

1 IPR2023-00480. Does that sound right?

2 A That sounds right.

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

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

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

12 A It does.

13 Q And what's that number?

14 A The number is EX1080.

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

18 A That is also my understanding.

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

22 A Correct.

1 Q And does it have an exhibit number in the
2 lower right-hand corner?

3 A It does.

4 Q And what's that number?

5 A EX1080.

6 Q Do you have any other hard copies of
7 documents with you today?

8 A The only hard copies of documents that I
9 have with me today are the two documents for which
10 I read the exhibit number for you.

11 Q Your declarations.

12 A That is correct.

13 Q Are those clean copies of your
14 declarations?

15 A Both copies are clean. There are no
16 annotations by anyone on either of them.

17 Q Great. Do you recall when you were
18 contacted to participate in this case?

19 MS. KHANDURI: Objection. Dr. Pinal, I
20 will remind you to -- I will caution you to not
21 divulge the substance of communications with
22 counsel. Subject to that instruction, you can

1 answer the question.

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

4 Q Do you recall when that was?

5 A Not precisely.

6 Q Do you have an estimate of when that was?

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

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

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

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

15 A I do.

16 Q Who was that?

17 A Ms. Bond.

18 Q Who is Ms. Bond?

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

21 Q Okay, and that firm's Sterne Kessler?

22 A That is correct.

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

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

6 Q Less than ten times?

7 A Less than ten times would be an adequate
8 estimate.

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

11 A Deposition testimony in general or for
12 IPR proceedings?

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

18 A In general, about 15 times.

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

22 A To the best of my recollection, this is

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

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

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

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

11 A I believe so.

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

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

20 A I did.

21 Q Yes or no, did you prepare with counsel?

22 A My preparation for this deposition

1 included meeting with counsel.

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

5 A It did not.

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

9 A My estimate is about five times.

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

12 A They did not.

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

15 A Three.

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

20 A The three attorneys here present.

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

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

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

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

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

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

16 Q What do you mean by for the most part?

17 A It also involved thought process of
18 connecting concepts.

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

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

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

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

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

9 A I have it in front of me.

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

12 A I am there.

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

15 A I see it.

16 Q Is that your signature?

17 A That is my signature.

18 Q And you signed this declaration on April
19 3rd, 2024.

20 A That is correct.

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

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

3 A I have it in front of me.

4 Q Can you please go to the last page there?

5 A I am on the last page.

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

8 A This is also my signature.

9 Q And you signed it?

10 A I did sign it.

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

12 A I signed it on April 3rd, 2024.

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

16 A That is correct.

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

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

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

1 of your understanding.

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

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

6 A Could you clarify the question?

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

10 A My declaration contains different aspects
11 of my general opinion.

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

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

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

19 A Okay.

20 Q Could you please turn to page 8?

21 A I am on page 8.

22 Q At paragraph 21, you write, "In

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

3 A I see it.

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

7 A I do.

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

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

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

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

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

19 A I see it.

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

1 A You did.

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

5 A I did consider Dr. Miller's declaration.

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

8 MS. KHANDURI: Objection, scope.

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

13 Q Did Dr. Miller's declaration of Exhibit
14 1002 include any opinions as to formulation?

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

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

19 A I review it. I did not memorize it.

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

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

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

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

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

14 MS. KHANDURI: Objection, form,
15 foundation.

16 A I don't understand your question.

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

19 A That is correct.

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

1 MS. KHANDURI: Objection, form,
2 foundation.

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

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

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

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

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

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

22 A I have not memorized Dr. Miller's

1 declaration.

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

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

6 Q Have you ever talked to Dr. Miller?

7 A I have not.

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

11 A I have not.

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

14 A He has not.

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

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

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

21 A I have not.

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

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

3 A I did not.

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

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

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

13 A To my knowledge, I don't know.

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

16 A I have paragraph 13 in front of me.

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

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

1 Q Is pharmacokinetics an aspect of your
2 expertise in pharmacology?

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

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

9 A I will be comfortable with that.

10 Q Is formulation an aspect of PK?

11 A Formulation is another subject that falls
12 under pharmaceutical sciences.

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

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

21 Q So what is, in your words, formulation?

22 MS. KHANDURI: Objection, form.

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

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

8 A Can you repeat your question please?

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

12 MS. KHANDURI: Objection, form, scope.

13 A I absolutely don't understand your
14 question.

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

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

1 subject.

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

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

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

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

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

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

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

22 A Solubility is one of the parameters that

1 is taken into account.

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

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

8 Q And what is permeability in this context?

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

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

16 A Could you clarify your question?

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

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

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

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

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

7 A I was consulting a footnote.

8 Q Which footnote was that?

9 A It is footnote number 2.

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

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

14 Q Is a solution another example of dosage
15 form?

16 MS. KHANDURI: Objection, form.

17 A Dosage forms include solutions.

18 Q Is sublingual film an example of a dosage
19 form?

20 MS. KHANDURI: Objection, form.

21 A Dosage forms include sublingual films.

22 Q Did you analyze any examples of

1 sublingual films as part of your analysis in this
2 case?

3 A I have no precise recollection of that.

4 Q Can you describe what a sublingual film
5 is?

6 A I can.

7 Q Could you please?

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

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

18 MS. KHANDURI: Objection, scope.

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

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

1 pharmaceutical sciences?

2 MS. KHANDURI: Objection, scope.

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

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

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

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

20 MS. KHANDURI: Objection, form,
21 foundation.

22 A The amorphous form of a material is one

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

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

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

11 Q Is stability another parameter considered
12 in the pharmaceutical sciences?

13 MS. KHANDURI: Objection, form,
14 foundation.

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

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

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

1 chemically intact for a prolonged period of time.

2 Q Is higher stability for a drug
3 preferable?

4 MS. KHANDURI: Objection, form,
5 foundation.

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

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

12 MS. KHANDURI: Objection to form.

13 A It depends.

14 Q On what?

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

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

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

1 Q And what do you mean by other
2 ingredients?

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

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

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

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

18 A There is.

19 Q What's that term?

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

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

4 A Can you clarify your question please?

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

10 MS. KHANDURI: Objection, form,
11 foundation.

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

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

22 A Patients, when they have to take

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

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

9 MS. KHANDURI: Objection, form.

10 BY MR. BERTULLI:

11 Q Is that fair?

12 A Can you clarify?

13 Q Yeah.

14 A What kind of --

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

1 MS. KHANDURI: Objection to form, scope.

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

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

10 MS. KHANDURI: Objection, scope, form.

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

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

16 A I have.

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

20 MS. KHANDURI: Objection, form.

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

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

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

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

8 MS. KHANDURI: Objection, form,
9 foundation.

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

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

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

2 A I would like to take a break.

3 Q Like right now or a couple more
4 questions?

5 A I would leave it up to you.

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

9 MS. KHANDURI: Objection, scope.

10 A I am.

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

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

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

20 MS. KHANDURI: Objection, scope, form.

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

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

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

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

9 A The physical scoring seen in dosage
10 forms.

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

14 MS. KHANDURI: Objection, form, scope.

15 A The term used for those lines is scoring.

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

19 MS. KHANDURI: Objection, form.

20 BY MR. BERTULLI:

21 Q Do you have that in mind?

22 MS. KHANDURI: Objection, scope, form.

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

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

9 MS. KHANDURI: Objection, scope, form.

10 A It could be.

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

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

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

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

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

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

7 Q Right, not a rule, but a preference.

8 MS. KHANDURI: Objection, form, scope.

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

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

14 THE WITNESS: Okay.

15 (Recessed at 10:07 a.m.)

16 (Reconvened at 10:21 a.m.)

17 BY MR. BERTULLI:

18 Q Welcome back, Dr. Pinal.

19 A Thank you.

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

1 administration?

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

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

8 MS. KHANDURI: Objection to form.

9 BY MR. BERTULLI:

10 Q -- of pharmaceutical product?

11 MS. KHANDURI: Objection, form.

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

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

16 A Oral delivery is frequently used to
17 administer pharmaceutical products.

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

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

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

5 A I do.

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

9 A Yes, there are.

10 Q Can you name them please?

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

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

15 MS. KHANDURI: Objection, form.

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

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

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

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

3 MS. KHANDURI: Objection, form.

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

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

12 MS. KHANDURI: Objection, form,
13 foundation.

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

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

20 MS. KHANDURI: Objection, form,
21 foundation.

22 A Bioavailability is a parameter in the

1 area of pharmacokinetics.

2 Q What is absolute bioavailability?

3 MS. KHANDURI: Objection, foundation,
4 form.

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

10 Q And what is relative bioavailability?

11 MS. KHANDURI: Objection, form,
12 foundation.

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

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

21 MS. KHANDURI: Objection, form,
22 foundation.

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

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

7 MS. KHANDURI: Objection, form,
8 foundation.

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

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

20 MS. KHANDURI: Objection, form.

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

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

4 MS. KHANDURI: Objection, form,
5 foundation.

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

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

12 MS. KHANDURI: Objection, form,
13 foundation.

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

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

19 MS. KHANDURI: Objection, form.

20 A In general, lower variability is
21 preferable.

22 Q Going back to bioavailability for a

1 second, can formulation affect bioavailability?

2 MS. KHANDURI: Objection, form,
3 foundation.

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

6 Q Can you have different formulations of
7 the same drug?

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

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

12 MS. KHANDURI: Objection.

13 BY MR. BERTULLI:

14 Q Yeah, maybe that's a weird question.

15 A Would you mind --

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

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

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

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

3 MS. KHANDURI: Objection, form.

4 A I think so.

5 Q Can you please give me one?

6 A Changing the composition would be a
7 change in formulation.

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

10 A Sorry.

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

13 A That doesn't make sense.

14 Q Okay. What's wrong with it?

15 A By changing the active --

16 Q That screws it all up?

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

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

3 MS. KHANDURI: Objection.

4 BY MR. BERTULLI:

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

6 MS. KHANDURI: Objection, form.

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

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

16 MS. KHANDURI: Objection, form,
17 foundation.

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

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

1 MS. KHANDURI: Objection, form.

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

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

7 MS. KHANDURI: Objection, form,
8 foundation.

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

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

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

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

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

1 MS. KHANDURI: Objection, form.

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

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

12 MS. KHANDURI: Objection, form,
13 foundation.

14 A It depends.

15 Q On what?

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

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

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

1 Q And what is a geometric mean?

2 A The geometric mean is the product of all
3 the observations raised to the inverse power of the
4 number of observations.

5 Q Can an arithmetic mean and a geometric
6 mean ever result in the same number?

7 MS. KHANDURI: Object to form.

8 A It is possible.

9 Q In the context of PK parameters, what is
10 a standard deviation?

11 A Standard deviation in the context of
12 pharmacokinetic parameters has the same definition
13 as in the context of traditional statistics.

14 Q And what is that definition?

15 A It is the summation of each observation
16 subtracting the mean raised to the square power
17 divided by the number of observations minus one and
18 the square root of that ratio.

19 Q How is a standard deviation used in the
20 context of pharmacokinetic parameters?

21 A Standard deviation is a measure of the
22 variability of the observations.

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

3 MS. KHANDURI: Objection, form.

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

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

13 MS. KHANDURI: Objection, form.

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

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

21 MS. KHANDURI: Objection, form,
22 foundation.

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

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

9 A I do.

10 Q Do you recognize Exhibit 1022?

11 A I do.

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

14 A This is the Bodor reference that I
15 considered.

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

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

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

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

1 Q Have you seen this particular document
2 that is Exhibit 1022 before your work in this case?

3 A To the best of my recollection, no.

4 Q And you'll see that there's a co-inventor
5 identified by this document, a Dr. Dandiker. Do
6 you see that?

7 A I see that.

8 Q Did you know Dr. Dandiker before your
9 work on this case?

10 A I did not.

11 Q So going forward, I'm going to try to
12 alleviate some confusion. When I say "Bodor," I'll
13 talk about the document going forward and not
14 Dr. Bodor the person.

15 A Understood.

16 Q And if that gets confusing, please ask me
17 for clarification.

18 A I will, thank you.

19 Q So you reviewed Bodor in its entirety as
20 part of your work on this case.

21 A I did.

22 Q Did you find any errors in Bodor?

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

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

5 MS. KHANDURI: Objection, form.

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

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

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

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

17 A I have table 6 in front of me.

18 Q What is Bodor showing in table 6?

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

1 parentheses, "N equals 12," closed parentheses.

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

5 A I see it.

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

9 A That is correct.

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

13 A That is what AUC stands for in
14 pharmacokinetic context.

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

18 A It stands for infinity.

19 Q And what does that mean in this context?

20 MS. KHANDURI: Objection, form.

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

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

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

7 A It denotes the word "time."

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

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

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

18 MS. KHANDURI: Objection, form.

19 A It depends.

20 Q What does it depend on?

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

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

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

9 MS. KHANDURI: Objection, form.

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

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

16 A I see it.

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

20 A I see it.

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

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

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

8 MS. KHANDURI: Objection, form.

9 A The ratio is the result of a division
10 calculation.

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

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

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

17 A I see it.

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

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

1 subcutaneous administration.

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

4 A I have table 8 in front of me.

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

7 A I see it.

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

11 A That is correct.

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

16 A I see it.

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

19 A I see it.

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

22 A I see it.

1 Q And would you understand that ratio to
2 correspond to the same ratio we looked at in table
3 6?

4 MS. KHANDURI: Objection, form,
5 foundation.

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

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

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

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

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

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

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

5 (Recessed at 11:07 a.m.)

6 (Reconvened at 11:21 a.m.)

7 BY MR. BERTULLI:

8 Q Doctor, welcome back.

9 A Thank you.

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

15 A I have page 34 in front of me.

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

18 A Correct.

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

22 A That is correct.

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

4 A That is correct.

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

8 A That is correct.

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

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

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

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

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

20 MS. KHANDURI: Objection, form.

21 A Lower interpatient variability is
22 preferable over higher interpatient variability

1 when administering drugs to patients.

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

4 A I have paragraph 76 in front of me.

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

10 A You did read it correctly.

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

15 MS. KHANDURI: Objection, form.

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

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

1 increased over the other's, right?

2 MS. KHANDURI: Objection, form.

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

7 Q And it could be lower. Is that true?

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

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

16 A I see it.

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

20 MS. KHANDURI: Objection, form.

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

1 be better, but it is at least comparable.

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

4 MS. KHANDURI: Objection, form.

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

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

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

15 Q Not increased.

16 MS. KHANDURI: Objection, form.

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

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

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

7 MS. KHANDURI: Objection, form.

8 A Can you repeat the question?

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

15 MS. KHANDURI: Objection, form.

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

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

1 words in paragraph 76?

2 MS. KHANDURI: Objection, form.

3 A Can you repeat the question?

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

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

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

1 MS. KHANDURI: Objection, form.

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

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

14 MS. KHANDURI: Objection, form,
15 foundation.

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

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

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

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

15 MS. KHANDURI: Objection, form,
16 foundation.

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

21 Q How would you define not close in your
22 answer?

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

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

13 MS. KHANDURI: Objection, form.

14 A Can you phrase your question without so
15 many negatives?

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

22 A Maybe the reporter can help me. I do not

1 recall having said not close.

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

10 A Thank you for the clarification.

11 Q Of course.

12 A Now let me clarify --

13 Q Please.

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

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

22 MS. KHANDURI: Objection, form, scope.

1 A In which context? Sorry.

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

5 A I see it.

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

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

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

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

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

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

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

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

1 Q So if I have a central value of ten, are
2 you with me?

3 A I am.

4 Q And we have a standard deviation of plus
5 or minus five, you still with me?

6 A I am.

7 Q Ten plus five would be 15; is that right?

8 A That is correct.

9 Q And ten minus five would be five; is that
10 right?

11 A Correct.

12 Q So the range in that case using the
13 standard deviations is five to 15; is that right?

14 A Correct.

15 Q So in trying to understand what the
16 magnitude is, is the magnitude ten because that's
17 15 at the top end minus five at the bottom end?

18 A That would be in that case the magnitude
19 of the spread of the data within one standard
20 deviation.

21 Q So I've already lost your earlier answer
22 now, but when you brought up the magnitude of the

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

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

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

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

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

15 MS. KHANDURI: Objection, form.

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

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

1 insignificant difference, right?

2 MS. KHANDURI: Objection, form.

3 A That depends.

4 Q On what?

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

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

13 MS. KHANDURI: Objection, form.

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

19 Q Sure.

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

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

4 MS. KHANDURI: Objection, form.

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

7 Q Is it a lot?

8 MS. KHANDURI: Objection, form.

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

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

14 MS. KHANDURI: Objection, form.

15 A I would not put it that way.

16 Q How would you put it?

17 A That it is not only one.

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

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

1 Q Is it a thousand?

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

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

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

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

18 MS. KHANDURI: Objection, form,
19 foundation.

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

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

8 Q Is developing a pharmaceutical product
9 hard?

10 MS. KHANDURI: Objection, scope, form.

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

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

18 MS. KHANDURI: Objection, form.

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

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

3 MS. KHANDURI: Objection, form.

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

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

17 (Recessed at 12:04 p.m.)

18 (Reconvened at 12:51 p.m.)

19 BY MR. BERTULLI:

20 Q Welcome back.

21 A Thank you.

22 Q I am going to hand you an exhibit

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

2 A I do have it.

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

5 A Correct.

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

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

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

16 A Sorry, which part? Which paragraph?

17 Q The figure 1 at the bottom --

18 A Figure 1.

19 Q -- of the page.

20 A I'm looking at figure 1.

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

1 case D capital A means cladribine?

2 A Yes, that is my understanding.

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

7 A I see it.

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

10 A I do.

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

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

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

20 A I see it.

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

1 A In my understanding, that is nanomolar.

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

4 MS. KHANDURI: Objection, scope.

5 BY MR. BERTULLI:

6 Q What does it mean?

7 MS. KHANDURI: Objection, form.

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

11 Q In a patient's plasma?

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

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

17 A I see it.

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

21 MS. KHANDURI: Objection, form,
22 foundation.

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

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

5 A Ten nanomolars is one tenth of 100
6 nanomolar.

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

9 MS. KHANDURI: Thank you.

10 BY MR. BERTULLI:

11 Q And do you have that one in hand?

12 A I do.

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

15 A That is correct.

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

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

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

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

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

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

14 A You did.

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

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

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

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

4 MS. KHANDURI: Objection, form.

5 A Figure 4 in Rice's paper shows a graph
6 with three sets of data in a plotted form. One
7 corresponds to a placebo, another one to cladribine
8 0.7 milligrams per kilogram, and another one
9 corresponds to cladribine 2.1 milligrams per
10 kilogram.

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

14 A That is what I see in the block.

15 Q And the set of data corresponding to
16 cladribine at 0.7 milligrams per kilogram appears
17 to be identified as open circles in Rice's figure
18 4; is that right?

19 A That is what I see in figure 4.

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

1 indicated by open circles?

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

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

11 A Forty-three of my declaration?

12 Q Yeah.

13 A I am on page 43 --

14 Q Okay.

15 A -- of my declaration.

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

19 A I see it.

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

22 A I will refer you to paragraph 80, where

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

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

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

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

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

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

1 bioavailability."

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

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

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

15 Q Okay.

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

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

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

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

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

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

14 A Yes, I do.

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

19 MS. KHANDURI: Objection, form.

20 A I don't think I understand your question.

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

1 Stelmasiak is insignificant. You remember that?

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

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

22 A The word "equivalent" as used in the

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

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

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

1 MS. KHANDURI: Objection, form.

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

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

14 MS. KHANDURI: Objection, form,
15 foundation.

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

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

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

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

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

12 MS. KHANDURI: Objection, form.

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

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

21 A I have it with me.

22 Q And is that a copy of the Stelmasiak

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

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

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

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

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

11 A To the best of my recollection, no.

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

14 A I was not.

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

18 A I do remember.

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

21 A I don't believe I have.

22 Q And have you ever encountered Rice, the

1 scientist, before your work in this case?

2 A I have not.

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

6 A I do remember.

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

10 A I don't believe so.

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

13 A I have not.

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

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

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

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

7 MS. KHANDURI: Objection, form.

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

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

17 A It is Stelmasiak's Exhibit 2043.

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

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

1 difference between Bodor's 35.7 to 52.1 percent
2 range and the prior art, and those Stelmasiak's, in
3 parentheses, 37 to 55 percent range is
4 insignificant. Now, this sentence is referring to
5 the prior art, which includes Stelmasiak's. Now,
6 if we look at paragraph 75, and actually, my
7 declaration, the 37 to 51 percent, the range that
8 appears there, this is from -- I don't know the
9 number, but there is Liliemark's paper published in
10 1997, and this number -- this range is captured in
11 that publication.

12 Now, if you go to the Liliemark 1992,
13 which is 2043, and if you go under results, on page
14 1515, on the seventh line, that shows the 55
15 percent, which is part of the prior art. So what I
16 put is Stelmasiak's in parentheses, I'm making
17 reference to the prior art. So the prior art in
18 one reference includes 37 to 51, in another
19 reference, includes 55, and that covers the range
20 that has been reported in the prior art.

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

1 to?

2 A I have it in front of me.

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

6 A I see it.

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

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

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

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

22 So for purposes of making general

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

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

8 A Oh, yes.

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

11 A I see it.

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

15 MS. KHANDURI: Objection, form,
16 foundation.

17 A I'm totally lost on that one.

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

20 A Okay.

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

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

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

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

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

22 Q Let's turn to page 37 of your

1 declaration, and you have a table up at the top.

2 Do you see the row where you have Liliemark 1992?

3 A I see it.

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

6 A I see it.

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

9 MS. KHANDURI: Objection, form.

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

12 Q Uh-huh.

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

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

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

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

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

1 come from. So at the top of page 37, for Liliemark
2 1992, you've identified 48 percent, comma, 55
3 percent. Do you see that?

4 A I see it.

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

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

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

14 A I see it.

15 Q Is it your understanding that Liliemark
16 '97 is trying to express that 37 percent is one
17 summary value, and 51 percent is another summary
18 value?

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

1 Q It's a range, sir, right?

2 A A range is ranges, so we are getting into
3 this difficulty because this is the range of
4 summary values, but each summary value has its own
5 range. So 37 is 37 plus/minus something, and 51 is
6 51 plus/minus something, but the purpose of this
7 type of publication, which is a review, serves no
8 purpose to extend the amount of text and
9 characters. The purpose is to provide the
10 information, which is 37 as a representative --
11 sorry, as a summary value, and 51 as a summary
12 value, not as precise values measured, because a
13 precise value is not measured.

14 Q So now, where Liliemark 1997 says 37 to
15 51 percent, I'm to understand that in Liliemark
16 '97, 37 to 51 percent is a range of ranges of
17 bioavailability?

18 MS. KHANDURI: Objection, form.

19 A If we want to get into what those numbers
20 are --

21 Q I do.

22 A And I'm using it to explain what it is.

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

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

14 MS. KHANDURI: Objection.

15 BY MR. BERTULLI:

16 Q -- for Liliemark '92?

17 MS. KHANDURI: Objection, form,
18 foundation.

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

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

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

5 A I am going to refer you to Liliemark
6 1992, and if we look -- it doesn't have a header,
7 but the abstract on the first page on the
8 right-hand side column, on the fifth line, you can
9 read that it says the bioavailability was 48
10 percent plus/minus eight percent. So going back to
11 your question, Liliemark is reporting 48 percent
12 plus/minus eight percent. Now, for the purposes of
13 today's -- today's exchange between you and me, we
14 have agreed that the 48 percent is what we would
15 call a representative value -- or sorry, a summary
16 value.

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

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

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

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

13 A I have it in front of me.

14 Q So am I right then that where you write
15 37 to 55 percent at the bottom of that paragraph,
16 37 to 55 percent is comprised of a range of summary
17 values collected from the prior art?

18 MS. KHANDURI: Objection, form,
19 foundation.

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

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

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

6 A I see it.

7 Q So what I'm trying to understand, if the
8 37 to 55 percent range is a range of summary
9 values.

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

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

18 MS. KHANDURI: Objection, form.

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

1 measuring bioavailability.

2 Q Do you still have your copy of Bodor?

3 A I do.

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

7 A I have table 6 in front of me.

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

10 A I am there.

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

13 A I see it.

14 Q Does that mean lower limit, upper limit?

15 A That is what my understanding is.

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

18 A I see it.

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

22 A That is correct.

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

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

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

11 A That is the ratio.

12 Q Is that the summary value?

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

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

22 MS. KHANDURI: Objection, form,

1 foundation.

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

5 Q What summary value would have calculated
6 that 43.1?

7 MS. KHANDURI: Objection, form.

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

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

16 MS. KHANDURI: Objection, form.

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

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

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

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

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

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

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

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

17 Q Is the 35.7 number a summary value?

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

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

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

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

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

12 MS. KHANDURI: Objection, form.

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

16 Q Does that mean it's a summary value?

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

21 Q So they are not the summary values.

22 MS. KHANDURI: Objection, form.

1 THE WITNESS: The summary values --

2 MS. KHANDURI: Foundation.

3 THE WITNESS: -- of what?

4 BY MR. BERTULLI:

5 Q You said, "The summary value is used for
6 reflecting the general range. This 35.7 to 52.1
7 represent the low and high ends of that range."

8 MS. KHANDURI: Objection, form,
9 foundation.

10 THE WITNESS: Those are the represent --
11 well, let me put it this way. The 35.7 and 52.1
12 are the summary values of the low end and high end
13 of the range.

14 MS. KHANDURI: Counsel, can we take a
15 break? We've been going for about an hour.

16 MR. BERTULLI: Yeah, let's take a break.

17 (Recessed at 2:03 p.m.)

18 (Reconvened at 2:19 p.m.)

19 BY MR. BERTULLI:

20 Q Doctor, welcome back.

21 A Thank you.

22 Q Could you please pick up the copy of Rice

1 that I gave you a little earlier?

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

3 THE WITNESS: Oh, okay.

4 MS. KHANDURI: Thanks.

5 THE WITNESS: Oh, got it. I put it back.

6 I have it in front of me.

7 BY MR. BERTULLI:

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

11 A I have figure 4 in front of me.

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

14 A I have paragraph 80 in front of me.

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

20 A You.

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

1 1.4 to 2 milligrams per kilogram," and then in
2 parentheses, it says a hundred milligrams or 140
3 milligrams, divided by 70 kilograms. Do you see
4 that?

5 A I do.

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

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

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

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

22 A Your question doesn't make sense.

1 Q Why not?

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

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

8 A Okay.

9 Q So is it your opinion that if Bodor's 100
10 to 140 milligram dose is given to a patient having
11 the 70 kilogram average weight, then the lymphocyte
12 profile will be similar to Rice's figure 4 for the
13 0.7 milligram per kilogram profile?

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

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

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

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

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

20 Q Okay, can you please now -- you can set
21 Rice aside. Can you please turn back to paragraph
22 76 of your declaration?

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

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

5 A I see it.

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

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

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

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

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

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

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

1 A Yes, I have it in front of me.

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

6 A Correct.

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

9 A I would say yes.

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

12 A That calculation will be correct.

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

15 A I do.

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

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

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

1 A I do.

2 Q Stelmasiak does not cite to Saven, does
3 it?

4 A Can you specify which specific reference
5 by Saven you refer to?

6 Q Yes, if you turn to page 10 of your
7 declaration --

8 A Okay, I have it in front of me.

9 Q This is the table of exhibits that you
10 considered in forming your opinions; is that right?

11 A It is.

12 Q Okay, and I think the third one up from
13 the bottom, Exhibit 1074 is Saven?

14 A I see it.

15 Q And there's the Exhibit 1074 is the Saven
16 you referred to in your declaration, right?

17 A The 1074 exhibit is the Saven I referred
18 to in my declaration.

19 Q Okay, and does Stelmasiak cite the Saven
20 that you refer to in your declaration?

21 A Stelmasiak cites Saven, but not this
22 specific publication.

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

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

6 Q Sure.

7 A But it's a different publication by
8 Saven.

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

13 A It is not.

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

16 A Albertioni is not cited by Stelmasiak.

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

19 A Liliemark 1997 is not cited by
20 Stelmasiak.

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

1 right?

2 A I do not have an M.D.

3 Q Have you ever yourself treated a patient?

4 A My work has not involved treating
5 patients directly.

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

8 A I have not diagnosed patients with a
9 disease.

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

12 A I have no specialized training on
13 multiple sclerosis.

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

16 A My previous work has not involved
17 cladribine.

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

21 A I have not.

22 Q And during the course of your deposition

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

3 A I did not.

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

7 THE WITNESS: Thank you.

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

10 (Recessed at 2:37 p.m.)

11 (Reconvened at 2:53 p.m.)

12 EXAMINATION BY COUNSEL FOR
13 HOPEWELL PHARMA VENTURES, INC.

14 BY MS. KHANDURI:

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

20 A I have a general recollection.

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

1 forth in your declaration?

2 A My opinion has not changed.

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

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

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

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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)

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

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

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

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

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

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

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

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



6
7 Karen Youg
8 NOTARY PUBLIC IN AND FOR THE
9 DISTRICT OF COLUMBIA

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11 My commission expires:
12 July 31, 2024
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