

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

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4 HELSINN HEALTHCARE, S.A. and
5 ROCHE PALO ALTO, LLC,

6 Plaintiffs,

7 -vs-

8 DR. REDDY'S LABORATORIES, LTD.,
9 DR. REDDY'S LABORATORIES, INC.,
10 TEVA PHARMACEUTICALS USA, INC.,
11 and TEVA PHARMACEUTICAL
12 INDUSTRIES, LTD.

13 Defendants.

14 _____
15 Clarkson S. Fisher United States Courthouse
16 402 East State Street
17 Trenton, New Jersey 08608
18 June 3, 2015

19 **B E F O R E:** THE HONORABLE MARY L. COOPER
20 UNITED STATES DISTRICT JUDGE

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22
23 Certified as True and Correct as required by Title 28, U.S.C.,
24 Section 753

25 /S/ Regina A. Berenato-Tell, CCR, CRR, RMR, RPR
/S/ Carol Farrell, CCR, CRR, RMR, CCP, RPR, RSA

*United States District Court
Trenton, New Jersey*

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1 APPEARANCES:

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Colloquy

1 (In open court. June 3, 2015, 9:30 a.m.)

2 THE COURT: Good morning, everyone.

3 ALL: Good morning, your Honor.

4 THE COURT: Ready to proceed?

5 I just had one procedural note as we begin today.

6 Yesterday, of course -- and please be seated -- we started the
 7 testimony, and there was reference to exhibits as we went
 8 along.

9 MR. LOMBARDI: Yes.

10 THE COURT: Could you place a statement on the record
 11 about the admission of exhibits into evidence and what you've
 12 agreed?

13 MR. LOMBARDI: well, the way I had anticipated this
 14 would work, your Honor, obviously, we exchanged exhibits as
 15 part of the pretrial process. I don't think we put any
 16 exhibits up about which there is any dispute, but what I was
 17 going to do, I have kept a running list of the exhibit numbers
 18 that we have used, and I was, at the end of this witness'
 19 testimony, would approach the podium and read into the record
 20 the exhibits that we had -- we had used, formally offer them.

21 Plaintiffs can then make their objections to any of
 22 them. I don't believe there would be any, but they can make
 23 whatever objections, and then they would be offered to your
 24 Honor that way.

25 MR. O'MALLEY: And I guess this is as good a time to

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I N D E X

<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
GIORGIO CALDERARI				
By Mr. Lombardi	9		143	
By Mr. O'Malley		76		169
By Mr. Sender		158		

<u>EXHIBITS</u>	<u>DESCRIPTION</u>	<u>ID.</u>	<u>EVID.</u>
DTX-1023			174

(Both Plaintiffs' and Defendants' exhibit lists to be supplied)

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Colloquy

1 bring this up as any: This has been -- they have taken, the
 2 defendants have taken a position that this is
 3 cross-examination.

4 THE COURT: Some of it is. I mean, some of it is
 5 just foundational direct, but certainly they have the right to
 6 approach as if the doctor were an adverse witness.

7 MR. O'MALLEY: Right. Consistent with that approach,
 8 we weren't given notice of any of the exhibits they would use.
 9 we asked why not, you know, the evening before, and they said,
 10 well, this is cross-examination.

11 So, that being the case, these exhibits -- our
 12 perspective is -- aren't being offered as evidence, they're
 13 impeachment, and we would argue that they're not admissible as
 14 evidence. There hasn't been evidentiary foundations laid for
 15 them as they go, such that we could evaluate them one at a
 16 time in case there's exceptions to that.

17 So we would object to the admission of these exhibits.

18 MR. LOMBARDI: well, I would say, your Honor, first,
 19 that I would be surprised if there's a legitimate objection to
 20 any of these exhibits, given that they are all -- I believe I
 21 have used all Helsinn documents. There may be an exception or
 22 two there.

23 But putting that aside, I know of no limitation -- just
 24 the fact that you use an exhibit on cross-examination doesn't

Colloquy

1 doesn't come into evidence.
 2 THE COURT: All right. Let me just cut through this.
 3 If a witness is going to be asked about an exhibit,
 4 it's either for impeachment purposes and isn't going to be
 5 offered into evidence; or if it's going to be offered into
 6 evidence, it must be offered into evidence before the witness
 7 is questioned further about it. You lay the foundation. You
 8 say now I offer this exhibit in evidence. There's an
 9 opportunity -- that is the formal way, as you all know, that
 10 documents come into evidence, and they should come into
 11 evidence before any substantial testimony about the document
 12 is elicited from any witness.

13 It sounds to me as if we should go through the formal
 14 process, or there should be a stipulation about the documents.

15 And let me just say to defendants that this is not a
 16 jury trial, and I do believe that it would be appropriate for
 17 defendants to give notice of -- as best they can -- their list
 18 of interrogation exhibits in advance.

19 MR. LOMBARDI: And, your Honor, that's fine, and
 20 we'll do that. I just -- so your Honor understands, under the
 21 procedure that we all agreed to, cross-examination exhibits
 22 were not to be disclosed in advance.

23 So if that's your Honor's rule, then it will be
 24 changing the rule. And what your Honor wants is fine, but it
 25 will be changing the rule, as I understand it, as to all

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Colloquy

1 forward.
 2 THE COURT: I'm making up a procedure. Other than
 3 that, we follow the formal Rules of Evidence procedure, which
 4 I think is cumbersome and unnecessary here. I just want to
 5 know -- at the end of the day I want to know what documents
 6 are in evidence and which are not. And for any substantial
 7 testimony from a witness I think the document should be in
 8 evidence even if it is on cross-examination.

9 MR. LOMBARDI: Well, my intention is to offer
 10 everything that I have used with this witness, and if we need
 11 to at the end of the testimony I can go through and indicate
 12 that the document there's no authenticity objection, there's
 13 no hearsay objection and offer it that way. And if they want
 14 to state an objection, I suppose they can. But I guess rather
 15 than go back right here at the start I'll do it at the end of
 16 the witness' testimony, and we'll see where it takes us.

17 THE COURT: Let's do this at the end of Dr. Calderari
 18 being the first witness up to bat. When you think you're
 19 finished with all of your questions for him, both sides, or
 20 even at the end of your direct, Mr. Lombardi, then take a
 21 recess, hand your adversary a list, go through the list
 22 together, and don't burden the record with unnecessary
 23 colloquy.

24 MR. LOMBARDI: We can do that, your Honor.

25 THE COURT: Is that acceptable, Mr. O'Malley?

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Colloquy

1 witnesses, and then all cross-examination witnesses must be
 2 disclosed -- exhibits, I apologize, must be disclosed in
 3 advance. That's what your Honor --

4 THE COURT: I would prefer that. It would make for a
 5 much smoother presentation.

6 MR. O'MALLEY: I would just offer a possible caveat.
 7 I mean, most of our cross-examinations are going to be
 8 impeachment, and I know I don't plan to offer most of the
 9 exhibits I use into evidence, and, therefore, it's not like
 10 what we're seeing today, so...THE COURT: well, I mean, I'm
 11 the trier of fact, and if I'm shown a snippet during
 12 cross-examination, and I can't go back and look at it later to
 13 see what it said, that places the trier of fact in a non-jury
 14 presentation at a disadvantage. So, please think it over.

15 MR. LOMBARDI: We can do that and we can talk after
 16 this witness about procedures going forward. The one thing on
 17 the exhibits generally, your Honor -- just to the extent it
 18 gives you some comfort -- the parties in the pretrial order
 19 agreed to the authenticity of all documents on the exhibit
 20 list that we have used. They agreed that all documents are
 21 within the business record exception to the hearsay rule. I
 22 don't think there is any relevance objections to any of them,
 23 and, so, I don't think that there's a legitimate basis to
 24 object to any of the documents that we have used, but I

Calderari - Direct

1 MR. O'MALLEY: Yes, your Honor.

2 THE COURT: Okay. Thank you.

3 You can proceed.

4 BY MR. LOMBARDI:

5 Q. Good morning, Doctor.

6 A. Good morning, Mr. Lombardi.

7 Q. Doctor -- and please just answer this question yes or
 8 no -- did you talk to your attorneys yesterday about your
 9 testimony?

10 THE COURT: Yesterday evening after court or this
 11 morning.

12 THE WITNESS: Yes.

13 BY MR. LOMBARDI:

14 Q. And did you talk to your attorneys about the testimony
 15 you're going to give today this morning? Again, a yes-or-no
 16 answer.

17 A. No.

18 Q. Did you talk to your attorneys last night about the
 19 testimony you were going to give today?

20 A. No.

21 Q. Thank you. Now, Doctor, yesterday -- just to orient you
 22 to where I'm going so that we're on the same page -- we talked
 23 about Phase II studies that were conducted by the scientists
 24 at Syntex concerning the formulations -- concerning

Calderari - Direct

- 1 A. Right.
- 2 Q. Okay. So, I want to ask you a little bit about the Phase
- 3 II studies. I think you mentioned -- just confirm for me if I
- 4 have this right -- that the studies, the Phase II clinical
- 5 studies that were done by Syntex...
- 6 First of all, those were done before 1995; is that
- 7 right?
- 8 A. That is right, yes.
- 9 Q. And you said, I believe, that the Syntex Phase II study
- 10 was done with palonosetron in a saline solution; is that
- 11 right?
- 12 A. Right.
- 13 Q. And the saline solution formulation with palonosetron is
- 14 different than the formulation that is -- appears in the
- 15 patents that we're here talking about today; is that right?
- 16 A. Right.
- 17 Q. Okay. Now, you know from your review back at the time
- 18 Helsinn became involved that Syntex suggested changes in the
- 19 formulation to be used with palonosetron to go into the Phase
- 20 III clinical studies and, ultimately, into commercial batches;
- 21 is that right?
- 22 A. Right.
- 23 Q. Okay. And, so, let's look at the -- we looked yesterday
- 24 at something called the Formulation Book. Do you remember
- 25 that?

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Calderari - Direct

- 1 exhibits are going to be offered and accepted into evidence at
- 2 the conclusion of this.
- 3 THE COURT: Is that acceptable to you?
- 4 MR. LOMBARDI: That is fine with me. I thought your
- 5 Honor had wanted -- so I just didn't want to shortcut it if I
- 6 shouldn't shortcut it.
- 7 THE COURT: That wasn't off the record, Mr.
- 8 O'Malley, it was all on the record.
- 9 MR. O'MALLEY: My apology.
- 10 THE COURT: If it is agreeable to you then you can
- 11 defer offering your exhibits into evidence, Mr. Lombardi,
- 12 until you finish with the direct of Dr. Calderari.
- 13 MR. O'MALLEY: For the record for this exhibit no
- 14 objection.
- 15 THE COURT: Okay. And I'm not going to admit it into
- 16 evidence yet. I will at the conclusion of the direct of Dr.
- 17 Calderari. And if there should be any objections then we will
- 18 still have Dr. Calderari here so that we can iron out the
- 19 objections and allow the full interrogation by both sides of
- 20 what he has to say.
- 21 MR. LOMBARDI: Thank you, your Honor.
- 22 THE COURT: Okay.
- 23 BY MR. LOMBARDI:
- 24 Q. Okay.
- 25 So, Doctor, within this book do you recall that there

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Calderari - Direct

- 1 A. I remember, yes.
- 2 Q. And the Formulation Book is a book you saw at the time
- 3 that you were doing the due diligence on the transaction with
- 4 Syntex; is that right?
- 5 A. Yes.
- 6 Q. So, let's look at DTX-0254, which you saw yesterday if
- 7 you recall, and we'll put it up on the screen for you.
- 8 A. Thank you.
- 9 Q. And there's the cover page. And do you see it says
- 10 "Formulation Book for Intravenous Dosage Forms"?
- 11 A. Yes.
- 12 Q. And the number at the top RS-25259-197 you understand is
- 13 Syntex's code name for palonosetron?
- 14 A. Right.
- 15 Q. And you see it is prepared by Roger Fu and dated
- 16 May 1995?
- 17 A. Yes.
- 18 Q. Can you identify Roger Fu for for the record?
- 19 A. He was a scientist working for Syntex.
- 20 Q. Is this the Formulation Book that you saw during the
- 21 course of due diligence at Helsinn?
- 22 A. Yes.
- 23 MR. LOMBARDI: I offer that, your Honor.
- 24 MR. O'MALLEY: Your Honor, I thought per our

Calderari - Direct

- 1 is specific discussion of the formulation for Phase III
- 2 clinical studies?
- 3 A. They had proposed theoretical formulation for Phase III
- 4 studies, yes.
- 5 Q. And let's go to Page DTX-0254-0018 of the document, and
- 6 let's show the top of the document so you can see what we're
- 7 looking at, Doctor. It says, "Proposed Marketed Formulations
- 8 and Phase III Clinical Formulations." That's the section of
- 9 the book that you just referred to; is that right?
- 10 A. Yes.
- 11 Q. And I believe we looked at this yesterday. But just to
- 12 remind you, if we blow the page out just a little bit, DJ, so
- 13 we can see the table, we looked at these formulations
- 14 yesterday, the 89 and the 90, and we really didn't talk about
- 15 the 91, but we looked at this table yesterday, correct?
- 16 A. We did, yes.
- 17 Q. All right. Now, Syntex talked about its rationale for
- 18 the formulation it was proposing for the Phase III clinical
- 19 studies in this book, didn't it?
- 20 A. Yes, they did.
- 21 Q. So, let's look at the next page, DTX-0254-0019, and the
- 22 title is actually "Formulation Rationale," correct?
- 23 A. Uh-huh.
- 24 Q. I'm sorry, you have to answer yes or no so the court

Calderari - Direct

- 1 coming up with Phase III clinical trial formulation; is that
2 right?
3 A. Sure, yes.
4 Q. But formulation that you decided to use in Phase III
5 clinical trials was not used in the Phase II clinical trials;
6 is that right?
7 A. Right.
8 Q. Because the Phase II clinical trials involved a saline
9 solution, while the Phase III clinical trials involved other
10 excipients that we've been talking about, correct?
11 A. Right.
12 Q. And you were willing, you made the decision at Helsinn to
13 put those -- that formulation into the Phase III clinical
14 trials without previously running Phase II clinical trials on
15 that formulation; isn't that right?
16 A. Right.
17 Q. Because you did not have concern for the safety of the
18 people in that clinical trial by using a formulation that had
19 not been previously tested, right?
20 THE COURT: Can you rephrase that?
21 BY MR. LOMBARDI:
22 Q. You at the time, at the time you went into Phase III
23 clinical trials, you weren't concerned about the safety of the
24 formulation you were going to put into those clinical trials.
25 A. No. We had no concern about the safety of the

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Calderari - Direct

- 1 rephrase it.
2 A. Maybe yes, thank you.
3 Q. I'll rephrase the term. There -- you said that this was
4 a risky situation?
5 A. Right.
6 Q. And you wanted to succeed in this situation.
7 A. Sure.
8 Q. You wouldn't have put this formulation into Phase III
9 studies unless you felt, you, yourself, and Helsinn felt that
10 it would succeed.
11 A. Mr. Lombardi, drug development is a risky, a risky
12 operation by given. There are so many attrition, there are so
13 many Phase III clinical trials that fail. It's part of the
14 entrepreneurial risk.
15 So we accepted several risks, and we thought we might
16 be able to manage; but we had no assurance that we would be
17 able at the end of the study to have a formulation with a
18 given concentration to alone to being stable and to the other
19 ends to have enough efficacious for treating emesis. We
20 didn't know at that time; and, therefore, we had to run a
21 Phase III clinical trial.
22 Q. Well, one thing you could have done to reduce your risk
23 is go back to Phase II clinical trials and use the formulation
24 that you ultimately used in Phase III. You could have done
25 that, couldn't you?

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Calderari - Direct

- 1 formulation itself.
2 Q. That's because you were familiar with all the excipients
3 and with palonosetron, and there were no safety concerns that
4 came to you at Helsinn; is that right?
5 A. Yes. For testing and phase clinical trial, yes.
6 Q. And you believed when you put this formulation --
7 THE COURT: For testing in Phase III clinical trials?
8 THE WITNESS: Right, yes.
9 BY MR. LOMBARDI:
10 Q. And you believed, when you chose this formulation for
11 Phase III clinical trials, you at Helsinn and you personally
12 believed that that formulation was going to be successful in
13 the Phase III clinical trials.
14 A. We had a hope that it would work, of course. We were
15 designing a plan with the hope at the end to have success.
16 Q. Well, you said yesterday that Phase III clinical trials
17 are a very important thing.
18 A. Yes.
19 Q. An important commitment for a company.
20 A. Right.
21 Q. A financial commitment for a company.
22 A. Right.
23 Q. There's a lot at stake.
24 A. There is a lot of?

Calderari - Direct

- 1 A. I mean, as I sit here now today, I could not speculate
2 with kind of hypothesis. We could have done others. I mean,
3 we, for sure, discussed many, many other options.
4 Q. Well, that was an option at the time, wasn't it?
5 A. I don't recall.
6 Q. Well, you know today, based on your experience in
7 clinical trials, that sometimes companies and sometimes the
8 FDA insists that you go back to Phase II clinical trials if
9 you're going to make a change in a formulation.
10 A. It can happen. It was not the case here. We got an
11 agreement with the FDA that we could go to Phase III.
12 Q. Exactly. So, I want to talk about two things.
13 One is from your point of view at Helsinn, you didn't
14 think it was necessary to go back to the Phase II clinical
15 trials with this formulation; is that right?
16 A. Yeah. We decided to take entrepreneurial risk to go
17 directly to Phase III.
18 Q. And the FDA also was comfortable with you going forward
19 with this formulation in Phase III despite the fact that it
20 hadn't been tested in Phase II.
21 MR. O'MALLEY: Objection as to "this."
22 THE WITNESS: You know the FDA, when it give --
23 THE COURT: It's all right.
24 THE WITNESS: I'm sorry.

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