UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs,

-vs-

DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Defendants.

CIVIL ACTION NUMBERS:

11-3962

TRIAL

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 2, 2015

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

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

/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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I N D E X

(In open court. June 2, 2015, 9:40 a.m.)

THE COURT: Good morning, everyone.

ALL: Good morning, your Honor.

THE COURT: Welcome. Today we start the trial in this consolidated action that's at docket number 11-3962. We'll start with opening statements. We may have a few minor matters to clear up before the opening statements are delivered, so let's all be seated, except for counsel, who are at counsel table who will state their appearances, starting with plaintiff.

MR. LIZZA: Good morning, your Honor. Charles M. Lizza of the Saul Ewing firm for the plaintiffs.

MR. O'MALLEY: Good morning, your Honor. Joe O'Malley, Paul Hastings, for plaintiff.

MR. DITTMANN: Good morning, your Honor. Eric Dittmann, Paul Hastings, also for plaintiffs.

MR. ASHKENAZI: Good morning, your Honor. Isaac Ashkenazi, Paul Hastings, also for plaintiffs.

MR. LOMBARDI: Good morning, your Honor. George Lombardi, Winston & Strawn, for Teva.

MR. WONG: Good morning, your Honor. Jovial Wong from Winston & Strawn for Teva.

MR. SENDER: Good morning, your Honor. Stuart Sender from Budd Larner for Dr. Reddy's Laboratories, defendants.

MR. WANG: Good morning, your Honor. Howard Wang

from Budd Larner for Dr. Reddy's.

MR. IMBACUAN: Good morning, your Honor. Michael Imbacuan from Budd Larner for Dr. Reddy's.

MS. HUTTNER: Good morning, your Honor. Connie Huttner from Budd Larner for Dr. Reddy's.

MS. TARANTINO: Good morning, your Honor. Mayra Tarantino from Lite DePalma Greenberg for Teva.

MR. CROWELL: Good morning, your Honor. Ken Crowell with Budd Larner for defendants Dr. Reddy's Labs.

THE COURT: I can't hear you, sir.

MR. CROWELL: Dr. Reddy's Labs.

THE COURT: Yes.

MR. CROWELL: Thank you.

MS. JOHNSON: Good morning, your Honor. Julia Johnson from Winston & Strawn for Teva.

MR. BARKER: Good morning, your Honor. Brendan Barker from Winston & Strawn for Teva.

THE COURT: Thank you very much. Welcome, everyone. Now, what have we got? I got a letter from Mr. Lizza, copy to everybody, about the other case, docket number 12-2867. I just wanted to acknowledge receipt of that. We don't need to discuss it right now.

And we got a letter from a nonparty Cipla Limited, et al., and they evidently are in litigation with Helsinn in the

part.
Q. Okay. And so it's clear on the record, could you tell the Court what a CMC is?
A. Yes. The CMC means chemistry manufacturing and control. It's all what about developing the API process and quality control, the drug product processes in quality control, up to having everything ready for the release and collecting all the necessary chemical stability data for filing a New Drug Application, and, yeah.
Q. Okay. Now, Helsinn, as you have said, has headquarters in Switzerland; is that right?
A. Is headquartered in Switzerland, yes.
Q. Okay. And it has a business strategy of in-licensing new chemical entities at a certain stage of development; is that right?
A. Yeah.
Q. And by in-licensing, you mean taking licenses from others who have come up with the new chemical entities; is that right?
A. This is right, yes.
Q. And then Helsinn's strategy is to complete the development process and, ultimately, manufacture and sell the product; is that right?
A. Well, not exactly, because during the phase that we are development, we seek partner for then that they can distribute

the product around the world. We do not have sales force directly, so it's a so-called B-to-B, business-to-business way of doing business, so...
Q. Okay. And Helsinn is not a drug discovery company; is that right?
A. Was not. Now in the meantime, we have some -- some drug discovery capacity.
Q. Fair enough. At the times that the work on palonosetron was going on, it was not a drug discovery company; is that right?
A. Yup.
Q. And Helsinn operated -- actually, the only patents you have in the United States are related to palonosetron; is that right?
A. Oh, I -- I can't recall.
Q. Okay. Helsinn operated, according to its business plan, this in-licensing plan, with respect to palonosetron; is that right?
A. Right, yeah.
Q. Didn't discover palonosetron?
A. No.
Q. Another company called Syntex discovered palonosetron; is that right?
A. Right.

record, I'm going to show you one of the patents just as an example just so that we can identify.
I'm going to show you the '219 patent, and that is DTX-0268. It's in your binders if you want, but I'm going to put it on the screen, and if you can't see it well enough on the screen, let me know. This is just the first page, and I'm going to blow it up for you, Doctor, so you can see it better.
MR. LOMBARDI: DJ, if we can just do the top half, say.
BY MR. LOMBARDI:
Q. Are you able to read that now, Doctor?
A. Yes.
Q. Okay. And So, you see this is the '219 patent on which you're listed as an inventor.
A. Right.
Q. And the other inventors are listed there where DJ has placed the cursor.
Do you see that?
A. I see that.
Q. And the patent -- well, this is the '219. Let's just skip back and just look at a claim here just so that we see that. Let's go to Column 10, which is Page 11 of the patent. That's where the claims are, Doctor.
Do you see that?
A. Yes.

Q. Okay. And let's just look at Claim 1. And you recognize that as one of the claims in the patent and one of the claims that's asserted here in this litigation; is that right?
A. I recognize, yes.
Q. Okay. And it's got the preamble language on reducing the likelihood of cancer chemotherapy, you see that?
A. I see that.
Q. And then it has the dosage of palonosetron. See that, at .25 milligrams?
A. Yes.
Q. And then it has a range for EDTA?
A. Yes.
Q. And it has a range for mannitol?
A. Yes.
Q. And it talks about being stable at 24 months; is that right?
A. Right.
Q. Okay. And you recognize, also, Example 4 in this patent, I'm going to move back a page, to Page 10. Example 4 has a particular formulation that fits within the ranges that we just talked about; is that right?
A. Right.
Q. And Example 4, the formulation that's there, is this the formulation for Aloxi®?

Q. Okay. And, so, this is a formulation that has the same, basically, the same plus a few of the ingredients we just looked at in the claim, Claim 1 of this patent; is that right?
A. Right.
Q. Now, it's true, isn't it, Doctor, that -- well, Syntex had been working on palonosetron for a period of time before Helsinn got involved; is that right?
A. Right.
Q. And Syntex got involved -- was working on it in the early '90s through roughly 1995; is that right?
A. Right, yes.
Q. And when did Helsinn first start considering a palonosetron product?
A. It was in 1997.
Q. Okay. And when Helsinn started considering a palonosetron product, they first looked to what Syntex had done; is that right?
A. Right.
Q. You obtained -- you were part of Helsinn's due diligence in considering entering into a transaction with Syntex; is that right?
A. This is correct.
Q. And being involved in that due diligence, you reviewed lots of documents, lots of scientific materials; is that right?

A. Is right, yes.
Q. And they were about palonosetron.
A. Yes.
Q. And one of the things that you discovered in your review of the scientific materials from Syntex when you first got involved is that the formulation of Example 4 had been arrived at by the folks at Syntex already; is that right?
A. No, this is not the formulation that we are using now that were in the documentation of Syntex at that time.
Q. Okay. Well, one of -- you got a few documents from Syntex, right? You got something called a preformulation book?
A. Right, yeah.
Q. And you got a document called the formulation book?
A. Yes.
Q. And that's where Syntex did work on coming up with a formula for a palonosetron I.V. administration product; is that right?
A. Can you say again?
Q. Yes. And any time you have trouble understanding, please tell me, and I'll try to reframe the question in a way that's understandable.

A formulation book in the case of Syntex's formulation book was a book where the scientific materials and rationale

product was kept; is that right?
A. Yeah, this is where they describe the attempt, their experiment to arrive to a formulation that might be suitable for clinical trial and then after for commercialization.

But to my surprise, when I made the first due diligence, they had never manufactured that formulation, that they had absolutely no any data about the stability of potential formulation to be used in a clinical trial.
Q. Okay. So it is clear, Doctor, I'm not asking you whether they had actually manufactured a formulation. I'm asking you whether they came up with the formulation that's in Example 4?
A. Not for the use in the CINV.
Q. Well, that wasn't my question either. I asked you did they come up with that formulation that's --
A. Can you show me the formulation book, please?
Q. Absolutely. But I'm just asking do you remember, as you sit here today, whether they came up with that formulation?
A. They came up? What do you mean, "came up"?
Q. Did they create that formulation?
A. They propose some formulations to be used in clinical trials for different indication.

THE COURT: Some formulations plural?

THE WITNESS: Some formulations, yes, plural.

THE COURT: Formulations.

THE WITNESS: Formulation, yeah. Remember, that

there are two indications in the emesis, one is the CINV in the morning, one is PONV and one is CINV. So they were proposing alternative formulation for use in clinical trials, depending on which indication you want to achieve.

BY MR. LOMBARDI:

Q. Okay. Is this one of the formulations that Syntex created?
A. Again, if you maybe show me the formulation book, it's easier because there are so many data in this picture.
Q. Okay.

THE COURT: Counsel, your question is whether Example 4 in the '219 patent spec is seen in the Syntex formulation book?

MR. LOMBARDI: Correct, your Honor. Correct.

BY MR. LOMBARDI:

Q. Let's look at DTX-0219, Doctor. And, again, I'll put it up on the screen. I'm sorry I said that wrong. DTX-0254. My apologies.
A. I wait anyway. Okay.
Q. Okay. Now, is that the formulation book that Syntex created?
A. Yes, it is.
Q. And you saw that shortly after Helsinn got involved in doing due diligence -- excuse me -- due diligence concerning

A. Well, shortly don't know, but for sure I had access to this document, yes.
Q. And you read this document; is that right?
A. Yeah, that's right, yes.
Q. And, so, Doctor, if you look at Page DTX-0254-0010, are there some formulations listed on that page?
A. Can you enlarge a bit?
Q. Yes, absolutely. Do you see formulations listed there?
A. Yes, I see that.
Q. And for the record so it's clear, you recognize the reference to RS-25259-197 to be to palonosetron.
A. Palonosetron hydrochloride, yes.
Q. Okay. And do you see that the ingredients listed there are the same ones that were in Example 4?
A. Yes.
Q. And do you see that for Formulation 90, the number 90, those are the same as appear in Example 4; is that right?
A. Yeah, but if I may qualify this, the Formulation 90 probably if you go a bit over in the -- in the file, they were suggested by Syntex to be used in clinical trial for achieving treatment of emesis in PONV.
Q. And I was going to get to that.
A. Yeah.
Q. But just bear with me for a minute. I promise you we'll talk about PONV --

A. Okay.
Q. -- and CINV.
A. Okay.
Q. Just bear with me for a minute.

If we compare that formulation, No. 90, to the formulation we just looked at in Example 4, they would be the same; is that right?
A. They would be the same in term of concentration; but, for example, I mean, when you create a dose for a clinical trial, you also have to speak about the volume. At the end is the final dosage that you use.

So the formulation in term of quality and quantity presence of excipient is the same, but they were meant to be used in another clinical trials than actually run, the CINV, and, also, the volume, the dose they would have proposed would be different because it was for a PONV indication.
Q. Okay. And just so it's clear, I'll just make it clear on the record.
A. Yeah.

MR. LOMBARDI: If you expand the column going up just a little bit, up, DJ, up from "Formulation."

BY MR. LOMBARDI:

Q. Right here it says, it identifies what Formulations 89 and 90 are.

A. I see that, yeah.
Q. And it says, "Formulation 89 has been selected for Phase III and commercial formulation for CIN" it says "E." We've been calling it CINV in this case. Same thing to you?
A. Yes, is the same things, yes.
Q. And then it says, "Formulation ending in 90 has been selected for PONV"; is that right?
A. This is right, yes.
Q. And PONV is post-operative nausea and vomiting; is that right?
A. Right, yes.
Q. Okay. But my question to you is just very simple --
A. Yeah.
Q. -- the actual formulation, whatever it's going to be used for of palonosetron in an I.V. formulation is there in this Syntex formulation book; is that correct?
A. Yes, it is correct.
Q. Okay. And Syntex actually was proposing at this time in the formulation book that this formulation would be used in Phase III clinical trials; is that right?
A. Yes, for PONV studies.
Q. And it wasn't long after you got involved that CINV became the focus of use of that formulation; isn't that correct?
A. Sorry, say again?

Q. It wasn't long after you and Helsinn became involved in the product -- in the project; I apologize. It wasn't long after you and Helsinn became involved in the project that that formulation that's in the Syntex formulation book, No. 90, was the focus of CINV studies; is that right?
A. Yeah, but, again, the formulation, yes, but the dose are totally different. I mean, at the end of the study, you want to have a formulation, but you have to have a dose to experiment in human being. Okay.
Q. Let me explain my question. I might not have made it clear.
A. Okay.
Q. That formulation for 90 --
A. Okay.
Q. -- that Formulation 90 --
A. Right.
Q. -- which right now is for use, selected for use in Phase III and commercial formulation for PONV, was switched to CINV; isn't that correct?
A. I think -- switched? It's not exactly what we did, I mean.
Q. Well, that formulation was used with CINV.
A. Was? Well, the composition of this formulation has been used, yes, but, again, with different volume.

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