UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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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.

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CIVIL ACTION NUMBER: 11-3962

TRIAL

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 11, 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

Colloquy

(In open court. June 11, 2015, 9:30 a.m.)

THE COURT: Good morning, all.

ALL: Good morning, your Honor.

THE COURT: Mr. O'Malley.

MR. O'MALLEY: Good morning. Your Honor, before we call our next witness, just a minor housekeeping item. From Dr. Candiotti yesterday, I believe we gave the court clerk a list of his exhibits, but I don't think we moved them into evidence. I have another copy of that list, if need be.

So, I just would like to move those exhibits into evidence.

THE COURT: Has the other side seen it?

MR. LOMBARDI: We'd just like -- we haven't seen the actual list that he's tendering, so we'd just like to see it. I don't anticipate any issues.

MR. O'MALLEY: It's just the exhibits that were --

MR. LOMBARDI: I don't anticipate an issue.

THE COURT: Okay. After the break then, you can move it in, Mr. O'Malley. All right?

MR. O'MALLEY: So with that, your Honor, we would like to call our next witness Dr. Carl Peck.

(Whereupon, CARL CURTIS PECK, witness for the Plaintiffs, sworn.)

THE DEPUTY CLERK: Please state and spell your full name for the record.

Peck - Direct

Have a seat.

THE WITNESS: Carl Curtis Peck.

MR. O'MALLEY: If I may approach, your Honor. I have the witness' exhibits. We've already distributed copies to the Court.

VOIR DIRE EXAMINATION BY MR. O'MALLEY:

Q. Good morning, Dr. Peck.

A. Good morning.

Q. Dr. Peck, could you please turn to Plaintiffs' Trial Exhibit 183.

Do you recognize this document?

A. I do.

Q. For the benefit of the Court, can you briefly describe your educational background after high school?

A. So, I spent three years at the University of Kansas in Lawrence and received a degree in mathematics and chemistry.

Following that, I took a Fulbright year in Germany studying physical chemistry at the University of Tübingen and the Technische Hochschule in Stuttgart.

Q. You may have to spell that, Dr. Peck. Do you have it? Never mind.

And go on.

A. Well, thereafter, I went back to Lawrence -- or to Kansas and attended medical school.

THE COURT: I think maybe this would be a good time for a break.

MR. O'MALLEY: Perfect. Your Honor. Thank you.

(Brief Recess.)

THE COURT: Thank you.

BY MR. O'MALLEY:

Q. Dr. Peck, did you hear Dr. Fruehauf provide some testimony regarding the results of Helsinn's Phase II 2330 study?

A. I did.

Q. Let's take a look at Defendants' Trial Exhibit 227. It's in one of the smaller separate notebooks in front of you. It will also be on the screen in front of you. What is this document?

A. So, this is the front page of the clinical section of the NDA, Item 8, and this content identifies the 2330 study report which will follow in Volume 104.

Q. And let's look at Defendants' Trial Exhibit 227-0005, near the bottom of the page. What do those dates indicate at the bottom of that page?

A. Right. So this is standard report -- reporting of certain milestones in the performance of a clinical trial, where the study date was started in May of 1994, the study date was completed on April 1995, meaning the last patient out, and the date of the report is July 1995.

Q. We've heard that term "last patient out" a few times during trial. What does that mean?

A. That's the date that the very last patient has exited the clinic or the study unit in a clinical trial.

Q. Okay. Now, have you prepared a slide summarizing Study 2230 [sic]?

A. I have.

Q. Let's please turn to Plaintiffs' Demonstrative Exhibit 209. And let's just take this a piece at a time. Can you summarize your opinion as to what the objective was of Study 2330?

THE COURT: Just again, this is Phase II?

MR. O'MALLEY: Phase II, correct.

THE COURT: Phase II. This is the Phase II study for what became Aloxi®, right?

BY MR. O'MALLEY:

Q. Can you answer that question, Dr. Peck?

A. So, there were five Phase II studies. This is one of them. It was an exploratory dose-ranging study in cancer patients who were receiving chemotherapy-induced nausea and vomiting -- who were experiencing that. It's an intravenous study. And the purpose of this was to evaluate graded doses to see the -- to evaluate the safety and to identify a possible signal of benefit.

A. Well, there were five dose groups that were administered. As you can see, they range from .3 to 90 micrograms per kilogram of body weight. There were a total of 161 patients. 24 patients were in the 3-microgram-per-kilogram group, a group of particular interest, but about the same number of patients were in each -- each of the others.

Most of the subjects were male. None of them had received a chemotherapeutic agent before, and basically, it was a small study that was quite unrepresentative of any, you know, broader population.

Q. And, by way of summary, what were the results of this study?

A. Well, I think we're going to see a richer table, but -- but there was the identification of one dose group, the 30-microgram-per-kilogram group, that yielded a statistically significant difference or finding for one of the outcome measures called complete control after 24 hours.

Q. Okay. Now, as you noted, we're going to dig into the details in a moment.

Were there any conclusions that could be drawn from Study 2330 regarding the efficacy of the solution that was tested?

A. Not in my opinion. There are -- there are a number of weaknesses of this study that would cause a POSA to be quite skeptical that even the 30-microgram-per-kilogram dosage would

work. For example, there was an incomplete dose-response pattern.

Q. Okay. Before explaining that, why don't we get to the table that you mentioned.

Let's look at Defendants' Trial Exhibit 227-0015. And let's blow up the area around the table. Do you understand what's set forth here?

A. I do. Now, this comes from the final study report of 2330. And it is the primary results of the -- of the potential for benefit. And what you see here are the doses lined up from .3 up to 90 and one --

Q. Would you like a pointer? I'm sorry to interrupt.

A. Oh, I'm sorry. Right, right, right, okay.

So, what you see in this row here are the dose assignments. As I say, there were about 25 subjects in each group. There were a couple of different ways of evaluating whether the drug was having an effect. One was called complete control and the other was called complete response. They differed very slightly, but each required that, you know, there be no -- no vomiting and retching and no requirement for rescue medicines.

And what you see here is that they -- they roughly line up here, but to compare with the lowest dose groups, .3 to 1, each of the others was statistically evaluated against that

result of the administration of the formulations that are at issue in this case?

A. Just saying that this table is not sufficient to inform me about any one person in the clinical trial.

Q. I didn't ask you about any one person.

I just asked you whether you can conclude that anybody in the trial actually experienced a reduction in the likelihood of CINV as a result of the administration of the formulation in this case?

A. The best you can say is that the raw data expressed as percentage differ among these groups, but you really must apply a statistical test, and in the case of a positive control like this, you have to confirm that the positive -- that the active ingredient, this is -- I mean, the active drug is actually working in this trial.

So there's a column missing, a very important column missing, and that's the historical placebo. This is a non-inferiority trial. And Dr. Fruehauf should have explained that a non-inferiority trial is never validated until it's compared with a historical control. And that's missing from this.

Q. Did you finish your answer?

A. I did.

Q. Okay. And so I'm just asking you, I think it's a "yes" or "no" question, okay? And so let me just ask you: Can you

tell from the data you're presented here whether anybody in this study received a reduction in the likelihood of CINV as a result of taking the formulations that are at issue in this case?

A. No.

MR. O'MALLEY: Objection, asked and answered.

MR. LOMBARDI: It's been -- it hasn't been answered.

THE COURT: He just answered.

THE WITNESS: I just answered "no."

MR. LOMBARDI: Thank you. Thank you.

Your Honor, if I could have a minute to confer.

THE COURT: Yes, always. Would you like to take a little recess?

MR. LOMBARDI: I think that would be the easiest thing to do.

THE COURT: That's fine.

MR. LOMBARDI: Thank you, Your Honor.

THE COURT: Okay.

(Recess taken.)

THE COURT: Mr. Lombardi?

MR. LOMBARDI: No further questions at this time, your Honor.

THE COURT: Fine. Thank you. Redirect.

REDIRECT EXAMINATION BY MR. O'MALLEY:

about a document entitled the FDA's Drug Review Process From Information For Consumers Database?

A. Yes, I do.

MR. O'MALLEY: I don't know if we're able to pull that up. If I can ask the help of Mr. Lombardi's hot seat guy. Thank you.

BY MR. O'MALLEY:

Q. Now, this appears to be two pages of text, and there's some, I don't know, cartoon figures in here. Have you seen this before?

A. Well, I think this was flashed up this morning or this afternoon --

Q. Before today?

A. I don't recall.

Q. Is this an FDA Guidance?

A. No, it's not an FDA Guidance. It's a communication to consumers to explain some aspects of drug development and regulation.

MR. O'MALLEY: Could we turn to Page 2 of this document, please.

BY MR. O'MALLEY:

Q. And you were asked some questions about the bottom of Page 2 regarding Phase II?

A. Yes.

Q. And in the middle of the paragraph, it states, "This

phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition."

Do you see that?

A. I do.

Q. Is this discussion in this consumer piece consistent with your discussion of Phase II clinical trials during my examination of you today?

A. Well, I believe it is, given that we see the word "preliminary" in there.

MR. O'MALLEY: Okay. Could we look at the conference report opportunities for integration and so on with Dr. Peck as first-named author. And, thank you, again, for the assist.

BY MR. O'MALLEY:

Q. You were asked some questions on Page 609 of this reference, and, in particular, towards the bottom on the left-hand column regarding Phase II.

Do you recall that?

A. I do.

Q. And, in particular, there's a statement here. I would like to direct you to towards about the third of the way down, "The principal goal of Phase II studies is to provide unequivocal evidence of the desired therapeutic effect."

Do you recall that?

A. I do.

consistent with your testimony regarding what Phase II clinical trials are about?

A. Yes, I think so. That's a goal. That's not always achieved, but that's a goal.

MR. O'MALLEY: Now, if we can turn to DTX-1019, and are you doing it or -- okay. 0009. Just wait till we switch over the hot seat. Thanks again.

BY MR. O'MALLEY:

Q. Now, I think you were asked some questions regarding the first paragraph. "The data suggests that the four higher-dose groups of palonosetron" and the dose groups were listed "were in general clinically more effective than the lowest-dose group," correct?

A. Yes.

Q. And before I get there, let me just, as the Court pointed out, there's -- the next sentence reads, "A statistically significant difference in the proportion of subjects with a complete response was achieved only for the comparison between .3-1 microgram per kilogram and 30-microgram-per-kilogram doses (24 percent versus 50 percent, respectively; p equals 0.047)."

Do you see that?

A. I do.

Q. That second sentence I read, is that consistent with your interpretation of the table from Study 2230 before the

reanalysis?

A. Yes, it is.

Q. Okay. Now, with respect to the first sentence, and specifically the words, "clinically more effective," Mr. Lombardi took you to several Helsinn or Syntex documents where they characterized the Phase II data in terms of clearly -- in terms of showing efficacy, the words varied.

Do you recall that?

A. I do.

Q. And I believe you said that that was the author's interpretation.

Do you recall that?

MR. LOMBARDI: And, Your Honor, I object. There's no foundation for this witness to testify as to what the author was doing. I think he said that during the cross-examination.

THE COURT: Well, I'll permit latitude on the redirect. Overruled as to this.

BY MR. O'MALLEY:

Q. Do you recall saying that?

A. I recall something like that, that representations by companies before FDA and various settings vary with respect to their championship and, you know, sort of attempt to persuade FDA, but it's -- it's just a matter of words.

Q. Now, you have said, I believe, that there was some

interpretations in these type of FDA documents.

A. I did.

Q. Do I recall that correctly?

A. I did.

Q. What did you mean by that?

A. Well, you know, this is a -- you know, when a company says this clearly shows, clearly, you know, that's a judgment call. It is a very positive qualification. It's sort of meant to persuade, and it's -- what FDA in advertising calls fluff. They permit a little fluff in advertising.

What they don't permit is submitting data that turns out to be fraudulent or incomplete. That's a very serious problem. But the way companies represent varies, and it varies within the company over time, and we've certainly seen this in this case.

Q. Now, with respect to this same document and this interpretation, you testified, I believe, that the FDA makes up its own mind.

Do you recall that?

A. Well, certainly.

Q. And what did the FDA decide with respect to Study 2230 specifically whether it was sufficient to show efficacy of any dose?

A. Well, this isn't the document I think that documents that, but in a 1999 meeting minutes with FDA, the FDA clearly

said that 2330, you know, would be admissible to the pivotal study. The data could be supportive. It didn't say this study report, it didn't say these results could be supportive, but it referenced the data.

Q. Now, if we could turn to DTX-0264.0009, and this is the table that's attached to the August Consulting letter requesting a meeting with the FDA.

Do you recall that?

A. I do. Yes, I do.

Q. Now, you testified in cross-examination something about a historical control missing?

A. Yes.

Q. Could you please explain what you meant by that.

A. I will. The term adequate and well controlled means that -- and it's very well accepted in the scientific community -- that in a randomized, blinded study, you compare the main effect of interest with a control group.

When --

THE COURT: The main what of interest?

THE WITNESS: The main effect, so, for example, in this case the reduction of nausea and vomiting and rescue medicines.

It must be compared and it must be compared under rigorous, statistical conditions. When the comparison group