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 NUMBER:

11-3962

TRIAL

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
June 5, 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

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/S/ Carol Farrell, CCR, CRR, RMR, CCP, RPR, RSA

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I N D E X

(In open court. June 5, 2015, 9:30 a.m.)

THE COURT: Good morning, everyone.

ALL: Good morning, your Honor.

THE COURT: Shall we continue?

MR. WONG: Yes.

THE COURT: Call your witness, Mr. Wong.

MR. WONG: Good morning, your Honor.

THE COURT: Call your witness, Mr. Wong.

MR. WONG: Sorry. I didn't hear you.

Just a bit of housekeeping. There were some exhibits that we didn't move into evidence yesterday from Dr. Fruehauf's testimony. If we can move them into evidence now. Just a couple of Exhibits. They are DTX-0015, DTX-0289 and DTX-0290.

MR. O'MALLEY: No objection.

THE COURT: Thank you. Those are admitted into evidence.

Just so you know, I have conferred with the court reporters and have told them not to put into the transcripts the admission of individual exhibits. Instead, we will rely upon the signed list that the parties give us at the end of the trial.

MR. WONG: Understood. Thank you.

Your Honor, today we're going to shift gears a little bit and talk about the obviousness of the claim formulations.

As our first witness, defendants call Dr. Lee Kirsch.

(Whereupon, LEE EDWIN KIRSCH, witness for the Defendant Teva, sworn.)

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

THE WITNESS: My name is Lee Edwin Kirsch, K-I-R-S-C-H.

LEE EDWIN KIRSCH, DEFENDANT TEVA'S WITNESS, SWORN,

VOIR DIRE EXAMINATION BY MR. WONG:

Q. Good morning, Dr. Kirsch.

A. Good morning.

Q. Dr. Kirsch, have you been asked to provide expert opinions in this case?

A. I have.

Q. And, in general, what do your expert opinions relate to?

A. They relate to the formulation in question and the invalidity of that formulation based on obviousness.

Q. Thank you. Let's review some background.

Dr. Kirsch, where are you currently employed?

A. I'm at the University of Iowa, faculty member at the University of Iowa in the College of Pharmacy.

Q. And what is your current position at the College of Pharmacy?

A. I'm a professor in the division of pharmaceutics and

A. Yes, I have.
Q. And in that -- was it a trial?
A. Yes, it was.
Q. And in that trial, what expertise did you offer?
A. I offered expertise in the development of formulations.

MR. WONG: Defendants tender Dr. Kirsch as an expert in the field of pharmaceutical formulation development with an emphasis on drug stability.

MR. O'MALLEY: No objection.

THE COURT: Admitted as such. Thank you.

DIRECT EXAMINATION BY MR. WONG:

Q. Let's get to your opinions, Dr. Kirsch.

Have you reviewed the asserted patents in this case?

A. Yes, I have.
Q. Are the asserted patents shown here on Kirsch 2?
A. Yes, there are four patents that I've considered.
Q. And, in general, what are the four patents about?
A. Well, the four patents are directed to the development of a stable formulation of the antiemetic drug palonosetron.
Q. Have you also reviewed the asserted claims in this litigation?
A. I have.
Q. And are the asserted claims up here on Kirsch 2 now?
A. Yes, that's correct.
Q. Have you identified a representative claim among the

eight asserted claims?
A. Yes. Claim 7 in the '219 patent really contains the elements that are relevant.
Q. And we'll get to each of these elements in a bit, but what is your general opinion regarding each of the components listed here for Claim 7?
A. Well, it's my opinion that these elements are a description or involve the description of a common -- commonly used conditions and components in I.V. formulations that are used for their common uses. So, in my opinion, this patent is invalid because of obviousness.
Q. Now, have you considered who a person of ordinary skill in the art would be with respect to the four patents?
A. Yes, I have.
Q. And who would that person be?
A. The person of ordinary skill in the art, a POSA, would be a formulation scientist typically with a Ph.D. in pharmaceutics or a related field and would have a couple of years of experience in developing I.V. formulations.
Q. Okay. Now, in your opinion, would this POSA have actual experience preparing formulations at the bench?
A. Yes.
Q. And what is the scope of resources that a POSA would draw upon when developing a formulation?

their academic training and experience. They would draw on the pharmaceutical science literature, general textbooks.

They would draw upon research articles and abstracts and other sources of information that gave them some idea of the current state of knowledge of palonosetron and related compounds, compounds that had a chemical or therapeutic similarity to palonosetron.

Q. Okay. And in the course of --

THE COURT: And patents, of course.

THE WITNESS: And patents, yes, they would certainly look at patents.

MR. WONG: Thank you.

BY MR. WONG:

Q. In the course of a POSA's practice, would he or she collaborate with others of ordinary skill in the art?
A. Yes, certainly they would. I mean, one of the mechanisms for that interaction, of course, is a project team; but even in the absence of a project team, they would draw upon the knowledge and expertise of clinicians and pharmacologists and other scientists in the field.
Q. So, that would be the same whether the POSA is working in industry or is in academia?
A. Yes, absolutely.
Q. Now, in forming your opinions in this case, what is the relevant date that you tied your opinions to?

A. So, the relevant date is January 30th, 2003.
Q. Okay. And as of January 30th, 2003, how would you describe the field of pharmaceutical formulation development?
A. Well, it was a well-established and well-trodden process by 2000 -- by the beginning of the 21st century. It had been practiced for some decades before, and successfully practiced.
Q. Okay. Let's talk a little bit about how a POSA would develop a pharmaceutical formulation.

Is there a standard formulation development process that a POSA would typically follow in developing a formulation?

A. Yes, there is.
Q. Have you prepared some slides to explain to the Court this process?
A. Yes, I have.
Q. Okay. This is Kirsch Demonstrative 4.

Dr. Kirsch, please explain the product development process that's up on this demonstrative from the standpoint of a formulator.

A. Right. So what I have tried to do in this picture is to describe the formulation development process, which is shown with these green boxes in the context of the overall development process, the clinical trial phase timeline.

And, so, you know, this is a typical -- the typical

LVPs, which are large volume parenterals, you know, which are typically the, you know, the liter bag of D5W or some other, you know, some other solvent that's slowly dripped into the patient.

BY MR. WONG:

Q. Okay. In addition to the routine formulation development activities and textbooks we just reviewed, what else would a POSA consider in developing an I.V. formulation?

A. So, of course, as we mentioned before, their training and their expertise, but they would also look to the available literature, the public literature that dealt with palonosetron and related compounds, therapeutically- and chemically-related compounds. So they would look to whatever is published that would inform them and would assist them in the design and development of their desired injectable formulation.

Q. Have you reviewed the relevant literature that a POSA would have considered with regard to developing palonosetron formulation?

A. Yes. So this was the, you know, the first thing that I did when I got involved in this -- in this situation, was to attempt to put myself in the position of a POSA as of 2003 and to do a search through the literature to see what -- what I found that -- that I thought would be relevant to a POSA.

Q. And for the record, did you only rely on publicly available documents of prior art in forming your opinions on

obviousness?

A. Yes.

Q. Have you prepared a slide that reviews the relevant prior art that a POSA would have uncovered?

A. Yeah, I put together a timeline that shows the publication dates of various documents and information that a POSA would likely use in helping them -- helping to inform them about what they need to do in the formulation development process.

Q. Okay. And we'll cover these individually as we move forward, but how would you characterize the prior art relevant to palonosetron prior to the filing date?

A. Well, there was quite a bit of information that was available in various forms that described palonosetron.

Q. Okay. And would these be -- would these references, these prior art, be helpful to a POSA in developing a palonosetron formulation?

A. Yes.

Q. So what is the first piece of prior art we'll review?

A. So, the first piece of art is the -- the product patent, the three -- what's called here the '333 patent published in 1993.

MR. WONG: Okay. And for the record, we're looking here at an excerpt of DTX-0343 on Page 1.

Q. You mentioned that the '333 patent was published in 1993. Who was the assignee of the '333 patent?

A. So, this was a patent that was generated by Syntex, the Syntex Research Group.

Q. And, in general, what does the '333 patent disclose to a POSA?

A. So the '333 patent is again a compound patent that describes an entire class of compounds of related -- chemically-related compounds which also they discuss some of their pharmacological properties as well, but, in particular, they describe the chemical structure of the -- of palonosetron in this -- in this patent.

Q. Let's go to the next slide. This is pages from DTX-0343 at 2 and 4.

Dr. Kirsch, what is disclosed here?

A. So, you know, this gives the general formula for the compounds that they disclose in the patent and then goes on to describe, you know, what chemical features at each of these positions -- R3, R2, and R1, that make up the chemical formulation of what later became known as palonosetron.

THE COURT: This chemical drawing that contains what you just said, R1, R2, and R3, as well as some actual chemical names, oxygen, right, nitrogen?

THE WITNESS: Right. So --

THE COURT: So R1, 2 and 3 are variables; is that

right?

THE WITNESS: That's correct.

THE COURT: Okay.

BY MR. WONG:

Q. So what does this next slide show, on Kirsch 13?

A. So this is the chemical structure, the assembled chemical structure of palonosetron, and also identifies that the -- the number that they gave it as part of the series. So the RS-26259 is the -- is the compound number for palonosetron that they refer to in the patent.

Q. Okay. And is the structure of palonosetron itself -- strike that.

The structure of palonosetron, would that be important to a POSA?

A. The formulator is definitely going to look at the structure because it will inform him, as a starting point, about potential issues with solubility. He can make some predictions about solubility based on structure. And, also, he will look at that structure to see whether or not there are particular types of structures in it, what we call moieties in it, which have the potential to undergo chemical instability.

THE COURT: What is the -- just out of curiosity, there is a two-letter abbreviation that's just sitting in the space there.

THE COURT: Deposition transcript maybe?

MR. O'MALLEY: Yes, that's what I intended.

BY MR. O'MALLEY:

Q. You haven't reviewed the deposition testimony of Dr. DeLuca either, have you?

A. I don't recall seeing it, no.

Q. Okay. So, that's fair to say you haven't taken any analysis of the extent to which, if any, Dr. DeLuca's opinions conflict with your own?

A. I have not conducted that analysis, no.

Q. Okay. Now, at your most recent deposition in this case, do you recall going through the various references that were listed on the face of the '219 patent with my associate and comparing them to the references you rely on for your obviousness opinion?

A. I do recollect having that discussion with him, yes.

Q. And do you recall him pointing out to you that each of the references you rely on are cited references on the face of the '219 patent?

A. I do recall that, yes.

Q. Okay. Now, I would like to look at the '219 patent, DTX-0248, Page 6.

MR. O'MALLEY: In the right-hand column, if you can find that for me, Roy. There we go.

BY MR. O'MALLEY:

Q. Do you see that your own expert report in this litigation is among the references cited on the face of the '219 patent?

A. Yes, I do see that.

Q. And do you understand, from the date, that that was the first expert report that you submitted in this litigation?

A. I believe that's correct.

Q. Okay.

THE COURT: There may have been a claim construction report separate from that expert report, but I'll allow you to question him.

BY MR. O'MALLEY:

Q. That report, if you need to verify my question, should be in your notebook.

A. Again, DTX-0268?

Q. Yes. So, if you'd turn to DTX-1175.

Do you see that?

A. Yes, I do see it.

Q. And let's turn to the back page for the date. There's an appendix, actually. There we go.

Do you see that's dated September 9?

A. Yes. I see it's dated that.

Q. Okay. And do you see that that's your first expert report you submitted in this litigation?

A. That is my recollection, yes.

you.

Do you see that?

A. Uh-huh.

Q. And do you see that this is the report whereby you summarize your opinions as to obviousness at least as to the first three patents-in-suit?

A. Yes, that's correct.

Q. Now, your opinions as to obviousness, do you have any difference in the structure of your opinions with respect to the '219 patent versus the first three patents-in-suit?

A. In general, I don't believe so.

Q. Okay. So, now going back to '219 references cited just to close the loop, Page 6, and there it is there.

Do you see, again, this expert report containing your opinions of obviousness, at least with respect to the first three patents-in-suit, is one of the references cited on the face of the '219 patent.

Do you see that?

A. Yes, sir, I do.

Q. Okay. Now, you've testified that you were first retained in connection with this action roughly towards the end of 2012 or maybe early 2013.

Do you recall that?

A. I believe that those dates are correct, yes.

Q. Okay. Now, let's look at Teva's invalidity contentions.

And I don't have a DTX number. They're in your notebook while we pull them up.

Oh, okay. Have you located those, or do you want to look at them from the screen?

A. The screen, I think, will be okay.

Q. Have you seen these before?

A. Yes, I believe I have.

Q. Okay. Now, let's look at Page 47.

Do you see the date for these contentions, December 1, 2011?

A. Yes.

Q. Yeah, and that's about a year before you were retained by Teva, correct? As best you recall?

A. As best as I recall, that's correct.

Q. Okay. Now, let's take a look at Page 4 of Teva's invalidity contentions.

Do you see there's a heading on Page 4 with the title "Identification of Prior Art Under L.Pat.R.3.3(a)"?

A. Yes, I see that title.

Q. And if you turn to Page 5, you see a list of references, correct?

Do you see that?

A. Yes, I do.

Q. And do you see the first reference is what the parties

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