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UNITED STATES DISTRICT COURT
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-

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

14

Defendants.

15

16 Clarkson S. Fisher United States Courthouse
17 402 East State Street
18 Trenton, New Jersey 08608
19 June 5, 2015

20 **B E F O R E:**

21 THE HONORABLE MARY L. COOPER
22 UNITED STATES DISTRICT JUDGE

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

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

United States District Court
Trenton, New Jersey

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1 **A P P E A R A N C E S:**

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25

*United States District Court
Trenton, New Jersey*

4

Colloquy

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

2 THE COURT: Good morning, everyone.

3 ALL: Good morning, your Honor.

4 THE COURT: Shall we continue?

5 MR. WONG: Yes.

6 THE COURT: Call your witness, Mr. Wong.

7 MR. WONG: Good morning, your Honor.

8 THE COURT: Call your witness, Mr. Wong.

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

10 Just a bit of housekeeping. There were some exhibits

11 that we didn't move into evidence yesterday from Dr.

12 Fruehauf's testimony. If we can move them into evidence now.

13 Just a couple of Exhibits. They are DTX-0015, DTX-0289 and

14 DTX-0290.

15 MR. O'MALLEY: No objection.

16 THE COURT: Thank you. Those are admitted into

17 evidence.

18 Just so you know, I have conferred with the court

19 reporters and have told them not to put into the transcripts

20 the admission of individual exhibits. Instead, we will rely

21 upon the signed list that the parties give us at the end of

22 the trial.

23 MR. WONG: Understood. Thank you.

24 Your Honor, today we're going to shift gears a little

25 bit and talk about the obviousness of the claim formulations.

*United States District Court
Trenton, New Jersey*

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I N D E X

<u>WITNESS</u>	<u>VOIR DIRE</u>	<u>DIRECT</u>	<u>CROSS REDIRECT RECROSS</u>
Lee Edwin Kirsch			
By Mr. Wong	5	18	
By O'Malley			92

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Kirsch - Voir Dire

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

2 (Whereupon, LEE EDWIN KIRSCH, witness for the

3 Defendant Teva, sworn.)

4 THE DEPUTY CLERK: Please state and spell your full

5 name for the record. Have a seat.

6 THE WITNESS: My name is Lee Edwin Kirsch,

7 K-I-R-S-C-H.

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

9 VOIR DIRE EXAMINATION BY MR. WONG:

10 Q. Good morning, Dr. Kirsch.

11 A. Good morning.

12 Q. Dr. Kirsch, have you been asked to provide expert

13 opinions in this case?

14 A. I have.

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

16 A. They relate to the formulation in question and the

17 invalidity of that formulation based on obviousness.

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

19 Dr. Kirsch, where are you currently employed?

20 A. I'm at the University of Iowa, faculty member at the

21 University of Iowa in the College of Pharmacy.

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

23 Pharmacy?

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

Kirsch - Direct

- 1 A. Yes, I have.
- 2 Q. And in that -- was it a trial?
- 3 A. Yes, it was.
- 4 Q. And in that trial, what expertise did you offer?
- 5 A. I offered expertise in the development of formulations.
- 6 MR. WONG: Defendants tender Dr. Kirsch as an expert
- 7 in the field of pharmaceutical formulation development with an
- 8 emphasis on drug stability.
- 9 MR. O'MALLEY: No objection.
- 10 THE COURT: Admitted as such. Thank you.
- 11 DIRECT EXAMINATION BY MR. WONG:
- 12 Q. Let's get to your opinions, Dr. Kirsch.
- 13 Have you reviewed the asserted patents in this case?
- 14 A. Yes, I have.
- 15 Q. Are the asserted patents shown here on Kirsch 2?
- 16 A. Yes, there are four patents that I've considered.
- 17 Q. And, in general, what are the four patents about?
- 18 A. Well, the four patents are directed to the development of
- 19 a stable formulation of the antiemetic drug palonosetron.
- 20 Q. Have you also reviewed the asserted claims in this
- 21 litigation?
- 22 A. I have.
- 23 Q. And are the asserted claims up here on Kirsch 2 now?
- 24 A. Yes, that's correct.
- 25 Q. Have you identified a representative claim among the

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Kirsch - Direct

- 1 their academic training and experience. They would draw on
- 2 the pharmaceutical science literature, general textbooks.
- 3 They would draw upon research articles and abstracts
- 4 and other sources of information that gave them some idea of
- 5 the current state of knowledge of palonosetron and related
- 6 compounds, compounds that had a chemical or therapeutic
- 7 similarity to palonosetron.
- 8 Q. Okay. And in the course of --
- 9 THE COURT: And patents, of course.
- 10 THE WITNESS: And patents, yes, they would certainly
- 11 look at patents.
- 12 MR. WONG: Thank you.
- 13 BY MR. WONG:
- 14 Q. In the course of a POSA's practice, would he or she
- 15 collaborate with others of ordinary skill in the art?
- 16 A. Yes, certainly they would. I mean, one of the mechanisms
- 17 for that interaction, of course, is a project team; but even
- 18 in the absence of a project team, they would draw upon the
- 19 knowledge and expertise of clinicians and pharmacologists and
- 20 other scientists in the field.
- 21 Q. So, that would be the same whether the POSA is working in
- 22 industry or is in academia?
- 23 A. Yes, absolutely.
- 24 Q. Now, in forming your opinions in this case, what is the
- 25 relevant date that you tied your opinions to?

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Kirsch - Direct

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

Kirsch - Direct

- 1 A. So, the relevant date is January 30th, 2003.
- 2 Q. Okay. And as of January 30th, 2003, how would you
- 3 describe the field of pharmaceutical formulation development?
- 4 A. Well, it was a well-established and well-trodden process
- 5 by 2000 -- by the beginning of the 21st century. It had been
- 6 practiced for some decades before, and successfully practiced.
- 7 Q. Okay. Let's talk a little bit about how a POSA would
- 8 develop a pharmaceutical formulation.
- 9 Is there a standard formulation development process
- 10 that a POSA would typically follow in developing a
- 11 formulation?
- 12 A. Yes, there is.
- 13 Q. Have you prepared some slides to explain to the Court
- 14 this process?
- 15 A. Yes, I have.
- 16 Q. Okay. This is Kirsch Demonstrative 4.
- 17 Dr. Kirsch, please explain the product development
- 18 process that's up on this demonstrative from the standpoint of
- 19 a formulator.
- 20 A. Right. So what I have tried to do in this picture is to
- 21 describe the formulation development process, which is shown
- 22 with these green boxes in the context of the overall
- 23 development process, the clinical trial phase timeline.
- 24 And, so, you know, this is a typical -- the typical

Kirsch - Direct

1 LVPS, which are large volume parenterals, you know, which are
 2 typically the, you know, the liter bag of D5W or some other,
 3 you know, some other solvent that's slowly dripped into the
 4 patient.
 5 BY MR. WONG:
 6 Q. Okay. In addition to the routine formulation development
 7 activities and textbooks we just reviewed, what else would a
 8 POSA consider in developing an I.V. formulation?
 9 A. So, of course, as we mentioned before, their training and
 10 their expertise, but they would also look to the available
 11 literature, the public literature that dealt with palonosetron
 12 and related compounds, therapeutically- and chemically-related
 13 compounds. So they would look to whatever is published that
 14 would inform them and would assist them in the design and
 15 development of their desired injectable formulation.
 16 Q. Have you reviewed the relevant literature that a POSA
 17 would have considered with regard to developing palonosetron
 18 formulation?
 19 A. Yes. So this was the, you know, the first thing that I
 20 did when I got involved in this -- in this situation, was to
 21 attempt to put myself in the position of a POSA as of 2003 and
 22 to do a search through the literature to see what -- what I
 23 found that -- that I thought would be relevant to a POSA.
 24 Q. And for the record, did you only rely on publicly
 25 available documents of prior art in forming your opinions on

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Kirsch - Direct

1 Q. You mentioned that the '333 patent was published in 1993.
 2 who was the assignee of the '333 patent?
 3 A. So, this was a patent that was generated by Syntex, the
 4 Syntex Research Group.
 5 Q. And, in general, what does the '333 patent disclose to a
 6 POSA?
 7 A. So the '333 patent is again a compound patent that
 8 describes an entire class of compounds of related --
 9 chemically-related compounds which also they discuss some of
 10 their pharmacological properties as well, but, in particular,
 11 they describe the chemical structure of the -- of palonosetron
 12 in this -- in this patent.
 13 Q. Let's go to the next slide. This is pages from DTX-0343
 14 at 2 and 4.
 15 Dr. Kirsch, what is disclosed here?
 16 A. So, you know, this gives the general formula for the
 17 compounds that they disclose in the patent and then goes on to
 18 describe, you know, what chemical features at each of these
 19 positions -- R3, R2, and R1, that make up the chemical
 20 formulation of what later became known as palonosetron.
 21 THE COURT: This chemical drawing that contains what
 22 you just said, R1, R2, and R3, as well as some actual chemical
 23 names, oxygen, right, nitrogen?
 24 THE WITNESS: Right. So --
 25 THE COURT: So R1, 2 and 3 are variables; is that

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Kirsch - Direct

1 obviousness?
 2 A. Yes.
 3 Q. Have you prepared a slide that reviews the relevant prior
 4 art that a POSA would have uncovered?
 5 A. Yeah, I put together a timeline that shows the
 6 publication dates of various documents and information that a
 7 POSA would likely use in helping them -- helping to inform
 8 them about what they need to do in the formulation development
 9 process.
 10 Q. Okay. And we'll cover these individually as we move
 11 forward, but how would you characterize the prior art relevant
 12 to palonosetron prior to the filing date?
 13 A. Well, there was quite a bit of information that was
 14 available in various forms that described palonosetron.
 15 Q. Okay. And would these be -- would these references,
 16 these prior art, be helpful to a POSA in developing a
 17 palonosetron formulation?
 18 A. Yes.
 19 Q. So what is the first piece of prior art we'll review?
 20 A. So, the first piece of art is the -- the product patent,
 21 the three -- what's called here the '333 patent published in
 22 1993.
 23 MR. WONG: Okay. And for the record, we're looking
 24 here at an excerpt of DTX-0343 on Page 1.

Kirsch - Direct

1 right?
 2 THE WITNESS: That's correct.
 3 THE COURT: Okay.
 4 BY MR. WONG:
 5 Q. So what does this next slide show, on Kirsch 13?
 6 A. So this is the chemical structure, the assembled chemical
 7 structure of palonosetron, and also identifies that the -- the
 8 number that they gave it as part of the series. So the
 9 RS-26259 is the -- is the compound number for palonosetron
 10 that they refer to in the patent.
 11 Q. Okay. And is the structure of palonosetron itself --
 12 strike that.
 13 The structure of palonosetron, would that be important
 14 to a POSA?
 15 A. The formulator is definitely going to look at the
 16 structure because it will inform him, as a starting point,
 17 about potential issues with solubility. He can make some
 18 predictions about solubility based on structure. And, also,
 19 he will look at that structure to see whether or not there are
 20 particular types of structures in it, what we call moieties in
 21 it, which have the potential to undergo chemical instability.
 22 THE COURT: What is the -- just out of curiosity,
 23 there is a two-letter abbreviation that's just sitting in the
 24 space there.

Kirsch - Cross

1 THE COURT: Deposition transcript maybe?

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

3 BY MR. O'MALLEY:

4 Q. You haven't reviewed the deposition testimony of Dr.

5 DeLuca either, have you?

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

7 Q. Okay. So, that's fair to say you haven't taken any

8 analysis of the extent to which, if any, Dr. DeLuca's opinions

9 conflict with your own?

10 A. I have not conducted that analysis, no.

11 Q. Okay. Now, at your most recent deposition in this case,

12 do you recall going through the various references that were

13 listed on the face of the '219 patent with my associate and

14 comparing them to the references you rely on for your

15 obviousness opinion?

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

17 Q. And do you recall him pointing out to you that each of

18 the references you rely on are cited references on the face of

19 the '219 patent?

20 A. I do recall that, yes.

21 Q. Okay. Now, I would like to look at the '219 patent,

22 DTX-0248, Page 6.

23 MR. O'MALLEY: In the right-hand column, if you can

24 find that for me, Roy. There we go.

25 BY MR. O'MALLEY:

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Kirsch - Cross

1 you.

2 Do you see that?

3 A. Uh-huh.

4 Q. And do you see that this is the report whereby you

5 summarize your opinions as to obviousness at least as to the

6 first three patents-in-suit?

7 A. Yes, that's correct.

8 Q. Now, your opinions as to obviousness, do you have any

9 difference in the structure of your opinions with respect to

10 the '219 patent versus the first three patents-in-suit?

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

12 Q. Okay. So, now going back to '219 references cited just

13 to close the loop, Page 6, and there it is there.

14 Do you see, again, this expert report containing your

15 opinions of obviousness, at least with respect to the first

16 three patents-in-suit, is one of the references cited on the

17 face of the '219 patent.

18 Do you see that?

19 A. Yes, sir, I do.

20 Q. Okay. Now, you've testified that you were first retained

21 in connection with this action roughly towards the end of 2012

22 or maybe early 2013.

23 Do you recall that?

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

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

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Kirsch - Cross

1 Q. Do you see that your own expert report in this litigation

2 is among the references cited on the face of the '219 patent?

3 A. Yes, I do see that.

4 Q. And do you understand, from the date, that that was the

5 first expert report that you submitted in this litigation?

6 A. I believe that's correct.

7 Q. Okay.

8 THE COURT: There may have been a claim construction

9 report separate from that expert report, but I'll allow you to

10 question him.

11 BY MR. O'MALLEY:

12 Q. That report, if you need to verify my question, should be

13 in your notebook.

14 A. Again, DTX-0268?

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

16 Do you see that?

17 A. Yes, I do see it.

18 Q. And let's turn to the back page for the date. There's an

19 appendix, actually. There we go.

20 Do you see that's dated September 9?

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

22 Q. Okay. And do you see that that's your first expert

23 report you submitted in this litigation?

24 A. That is my recollection, yes.

Kirsch - Cross

1 And I don't have a DTX number. They're in your notebook while

2 we pull them up.

3 Oh, okay. Have you located those, or do you want to

4 look at them from the screen?

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

6 Q. Have you seen these before?

7 A. Yes, I believe I have.

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

9 Do you see the date for these contentions, December 1,

10 2011?

11 A. Yes.

12 Q. Yeah, and that's about a year before you were retained by

13 Teva, correct? As best you recall?

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

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

16 invalidity contentions.

17 Do you see there's a heading on Page 4 with the title

18 "Identification of Prior Art Under L.Pat.R.3.3(a)"?

19 A. Yes, I see that title.

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

21 correct?

22 Do you see that?

23 A. Yes, I do.

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

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