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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., et al., : Civil No.  
10-cv-5954 (WHW)  
Plaintiffs, :  
v. : TRANSCRIPT OF  
TRIAL PROCEEDINGS  
LUPIN LIMITED, et al., : VOLUME 1  
Defendants. :  
-----x

Newark, New Jersey  
March 18, 2014

BEFORE:

THE HON. WILLIAM H. WALLS, U.S.D.J.

Reported by:  
CHARLES P. McGUIRE, C.C.R.  
Official Court Reporter

Pursuant to Section 753, Title 28, United States  
Code, the following transcript is certified to be  
an accurate record as taken stenographically in  
the above entitled proceedings.

s/CHARLES P. McGUIRE, C.C.R.

CHARLES P. McGUIRE, C.C.R.

1 THE COURT: I expect both sides to be wary and  
 2 alert to the interests of their clients insofar as any  
 3 alleged trade secrets are concerned. I shall rely upon  
 4 their competence, and at this point, there's not been  
 5 demonstrated to me any need to say I will close the  
 6 courtroom to people, to members of the public.  
 7 As a matter of fact, from a very practical  
 8 standpoint, I doubt any members of the public, given the  
 9 choice, would be sitting in. All right?  
 10 MS. MAZZOCHI: I understand that, Your Honor.  
 11 Thank you.  
 12 THE COURT: Now, can I now turn to the motions in  
 13 limine?  
 14 MS. MAZZOCHI: Yes.  
 15 THE COURT: I told you we will take them in the  
 16 order in which I will deal with them because that will be  
 17 easier for everyone.  
 18 MS. MAZZOCHI: Thank you, Your Honor.  
 19 THE COURT: All right.  
 20 MS. MAZZOCHI: Although if it would be easier,  
 21 Your Honor, one thing that we did want to suggest is that  
 22 because there's a small number, only one or two witnesses  
 23 that are potentially going today and tomorrow, we would be  
 24 willing to address certain things when we get closer to  
 25 that.

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1 THE COURT: With regard to tomorrow, I have some  
 2 other matters that will occupy me, and I don't think I can  
 3 -- what's tomorrow; Wednesday, right?  
 4 And I don't think I can start and get you until  
 5 about 11, between 11 and 11:30. I have some sentences.  
 6 Yes?  
 7 MR. DISKANT: Your Honor, I would join with the  
 8 view that the in limine's be put off until we need them.  
 9 My concern is, we have two witnesses this week.  
 10 Dr. Stoffels is our first witness, and he'll be on maybe an  
 11 hour and a half or so, but our next witness, Piet Wigerinck,  
 12 does not work for our company, he came over from Belgium to  
 13 testify, and I'm very concerned, since we're not sitting on  
 14 Thursday, about whether we can get in all of this testimony  
 15 and cross-examination. So I was going to ask --  
 16 THE COURT: So you join in seeking that we  
 17 postpone the determination of the in limine matters; is that  
 18 right?  
 19 MR. DISKANT: Yes, I do, Your Honor. And I may  
 20 ask if Your Honor can sit late, depending on how we go.  
 21 We'll see how the day goes.  
 22 THE COURT: Well, I expect to sit until 4:30  
 23 today.  
 24 MR. DISKANT: Okay.  
 25 THE COURT: Is that all right?

1 MR. DISKANT: Thank you.  
 2 THE COURT: If that be the case, do you wish to  
 3 make your opening statements, or do you want to forego  
 4 those, too?  
 5 MR. DISKANT: I was going to make an opening.  
 6 Should I forego it? I'll make --  
 7 THE COURT: If you would be willing to make the  
 8 sacrifice.  
 9 (Laughter)  
 10 MR. DISKANT: I'll make an opening, but I'll be --  
 11 MR. RAKOCZY: One quick housekeeping matter, Your  
 12 Honor.  
 13 William Rakoczy for the Mylan Lupin Defendants.  
 14 THE COURT: Yes.  
 15 MR. RAKOCZY: How would Your Honor like to handle  
 16 objections to exhibits and demonstratives for each  
 17 particular witness; s they come, or before?  
 18 THE COURT: Well, upon their proffer.  
 19 MR. RAKOCZY: Pardon?  
 20 THE COURT: Upon their proffer.  
 21 MR. RAKOCZY: Okay. Thank you, Judge.  
 22 THE COURT: So are we going to have opening  
 23 remarks now?  
 24 MR. DISKANT: Yes, sir.  
 25 THE COURT: Is that why you brought everybody from

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1 the firm?  
 2 MR. DISKANT: There are a couple back there.  
 3 THE COURT: All right. Let's go. Go ahead, sir.  
 4 MR. DISKANT: Thank you.  
 5 At any rate, Judge, we're very, very pleased to be  
 6 here today, finally, after a long time in discovery for what  
 7 is for us a very, very important case.  
 8 Janssen, the Plaintiff, is the pharmaceutical arm  
 9 of Johnson & Johnson, the world's largest health care  
 10 company, and the drug that we're talking about is called  
 11 Prezista, which is the leading protease inhibitor in the  
 12 market. You're going to hear a lot about what that means,  
 13 but basically, there's a cycle to the HIV virus, and  
 14 scientists have attempted to intervene at many places along  
 15 the cycle. The protease is one of them, and if you can  
 16 block the protease, you can inhibit it, you can stop the  
 17 virus from replicating, and that's what this drug does. It  
 18 has sold \$1.7 billion in sales last year, one million  
 19 prescriptions. It's keeping people alive for years with no  
 20 detectable trace of HIV in their body, something that would  
 21 have been unheard of a generation ago.  
 22 We remember the AIDS -- the Defendants, of course,  
 23 are Mylan, Lupin, and Teva.  
 24 The AIDS crisis of the 80's was a horrifying time  
 25 for all of us who lived through it. It seemed like the

38

1 familiar with them from the motions. One is on making this  
2 bis-THF, the left-hand side of the molecule; one is on  
3 making the whole molecule and tacking on the bis-THF, and  
4 one is making the ethanolate form of the molecule.

5 All of this work was supervised by Dr. Piet  
6 Wigerinck, who will also be here to testify from Belgium,  
7 and in all cases, he came up with a formulation that went  
8 against the conventional wisdom and that resulted in a pure  
9 and efficacious commercial-scale process.

10 Very simply, I'll review the three patents and our  
11 claims and sit down.

12 Bis-THF is the first patent. This is the  
13 left-hand side. It's got three chiral centers. It's very  
14 difficult to fabricate, covered by the '015 patent, and Your  
15 Honor has found that both Teva and Lupin infringed that  
16 patented process precisely. So there's no infringement  
17 issue in the case. The only issue in the case is the  
18 validity of the '015 patent, and we will show that it is a  
19 novel patent, it is not something that's taught in the prior  
20 art, it starts with an unstable intermediate, it's not  
21 commercially available, it goes through a nitromethane step  
22 that is dangerous, it provides exquisite stereoselectivity  
23 so that it's possible to get exactly the right bis-THF that  
24 works in the fight against AIDS.

25 The next patent is the '411 patent. That's on

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39

1 darunavir synthesis, also designed by Pete Wigerinck. Your  
2 Honor has already found that Mylan infringes that patent,  
3 meaning the only issue for trial is going to be the validity  
4 of this patent, and this patent also is a valid patent. It  
5 is different than anything in the prior art. There were  
6 three prior processes. This is better and innovative. It  
7 uses a protecting group that increases the yield, that uses  
8 a novel coupling agent, that increases the yield even  
9 further and yields a pure product suitable for commercial  
10 manufacture.

11 And the last of the patents is the ethanolate  
12 patent. The ethanolate is a crystal structure that's very  
13 unusual, depicting here the crystal structure with channels  
14 running through it. The channels contain ethanol, making it  
15 ethanolate. And basically, we have claims against all three  
16 Defendants on the ethanolate patent.

17 Lupin admits that it uses darunavir ethanolate.  
18 Teva makes a darunavir hydrate, which it claims is different  
19 and we claim is equivalent. And Mylan makes, according to  
20 its published patent application, an amorphous form of  
21 darunavir which we contend contains traces of ethanolate  
22 because it starts with the ethanolate and can't get rid of  
23 them.

24 The issues for trial are going to be whether  
25 that's infringed and also whether the patent is valid. We

40

1 say and the proof will show that it is a novel and unusual  
2 form of a crystalline structure, a valid patent.

3 That's basically it. We've sold a million  
4 prescriptions last year, keeping people alive, and we would  
5 like to keep on doing that under our patents.

6 Thank you, Judge.

7 THE COURT: Thank you.

8 Who do I -- yes, sir.

9 MR. RAKOCZY: Good morning, Your Honor.

10 William Rakoczy again for the Mylan and the Lupin  
11 Defendants.

12 Your Honor, we submit the evidence will require a  
13 finding of noninfringement for Mylan on the '645 patent.  
14 Mylan does mount a noninfringement defense to that patent,  
15 and the evidence will also clearly and convincingly show that  
16 all three patents against Mylan and Lupin are invalid for,  
17 amongst other reasons, obviousness, which is the defense  
18 I'll focus on. There are other defenses in the pretrial  
19 order and that you will hear about from the experts.

20 Your Honor obviously knows about the asserted  
21 claims of the patents-in-suit. I will just note for the  
22 record, Your Honor, from the proceedings yesterday, again,  
23 our understanding is now it's just 1 and 4 from the '645, 1,  
24 claim 1 from the '015 and claim 13 from the '411. My  
25 understanding is all claims will be dismissed with prejudice

**CHARLES P. McGUIRE, C.C.R.**

41

1 and that will be the battleground for trial.

2 THE COURT: I so ordered the stipulations that you  
3 and the other side worked out.

4 MR. RAKOCZY: Okay. I had not seen it, Your  
5 Honor.

6 THE COURT: Oh, you haven't even seen it.

7 MR. RAKOCZY: Okay.

8 THE COURT: Well, go ahead. I signed it this  
9 morning, but go ahead.

10 MR. RAKOCZY: And you heard very briefly that  
11 darunavir falls into this class of protease inhibitors, also  
12 known as PIs. They are so named because they inhibit life  
13 protease. The only one thing I wanted to emphasize for  
14 background, Your Honor, so I can move along here is that I  
15 think you heard from Janssen basically that the challenge in  
16 this case, he said, is about a method of making darunavir  
17 and formulating darunavir.

18 This case and the patents-in-suit are not about  
19 the darunavir molecule or the darunavir compound and any of  
20 its properties and clinical benefits.

21 Darunavir is an old molecule. It was already  
22 tested and its anti-HIV properties were known as early as  
23 1988. It was in clinical trials by February 2002. So this  
24 case is not about designing a new darunavir molecule. That  
25 molecule was old and in the prior art. Matter of fact, it's

102

1 Q. Counsel just said a moment ago that, for example, the  
2 formulation of Prezista had nothing whatever to do with  
3 these results. Do you agree with that?  
4 A. I do not agree with that.  
5 Q. Why not?  
6 A. Because you -- we were -- without all the chemical and  
7 pharmaceutical work, we never would have been able to give  
8 the drug to patients.  
9 Q. And indeed, you told us earlier about the drug  
10 Intelence. Do you recall that?  
11 A. Yes.  
12 Q. Which went from 36 pills to one or two a day?  
13 A. Two a day, yes.  
14 Q. Did the formulation matter?  
15 A. Absolutely.  
16 Q. Does the formulation matter for the success of  
17 Prezista?  
18 A. Absolutely.  
19 Q. How about the process? You said it didn't matter --  
20 THE COURT: Remember you're on direct.  
21 MR. RAKOCZY: I'm sorry?  
22 THE COURT: You're on direct.  
23 MR. RAKOCZY: Okay.  
24 THE COURT: All right?  
25 Q. Let me ask it this way: Did the process have any

**CHARLES P. McGUIRE, C.C.R.**

103

1 effect on these results?  
2 A. We were able to make the compound, and that benefited  
3 the patients.  
4 Q. You talked earlier about your friend Jens that you  
5 treated in '95 or thereabouts. Tell us how he came to be  
6 treated with Prezista.  
7 (Mr. Rakoczy rises)  
8 A. He failed --  
9 THE COURT: I agree. We don't need to hear this.  
10 Let's move on. He already told us that he was still alive  
11 as of 2014. Go ahead.  
12 Q. When did FDA approve Prezista?  
13 A. In June 2006.  
14 Q. And look at PTX-591. Is that the press release  
15 announcing its approval?  
16 A. Yes, the FDA commissioner issued a press release  
17 telling the importance of the discovery and -- for patients.  
18 Q. Is Prezista recommended by the Department of Health  
19 and Human Services for treatment?  
20 A. Yes, it's one of the two drugs that they recommend,  
21 protease inhibitors recommended by Health and Human  
22 Services.  
23 Q. And what's the other drug?  
24 A. Atazanavir.  
25 Q. And is there recent controlled clinical trials

104

1 comparing atazanavir with --  
2 A. Yes, recent control trials show that Prezista is  
3 superior.  
4 MR. RAKOCZY: Again, objection, Your Honor.  
5 THE COURT: I agree. I sustain the objection.  
6 MR. RAKOCZY: Thank you, Your Honor.  
7 THE COURT: You know my head is bowed. I'm  
8 ignoring you. Go ahead.  
9 MR. DISKANT: Okay. We're moving on.  
10 THE COURT: Go ahead.  
11 MR. DISKANT: Okay.  
12 Q. Today, let's talk about prescriptions for Prezista.  
13 How have they grown over the years and how many are there  
14 now?  
15 A. Today there are about one million prescriptions for  
16 Prezista.  
17 MR. RAKOCZY: Objection.  
18 MR. DISKANT: This is commercial success.  
19 THE COURT: I don't think there is any challenge  
20 that is meaningful as to the -- and I mean this quite  
21 deliberately -- the effectiveness of Prezista, nor its  
22 worldwide appeal. I don't think anyone's challenging that.  
23 And so that's already an issue that is not an issue.  
24 MR. DISKANT: There is a challenge to --  
25 THE COURT: As to what?

**CHARLES P. McGUIRE, C.C.R.**

105

1 MR. DISKANT: As to the commercial success of  
2 Prezista.  
3 THE COURT: Are you challenging commercial success  
4 of this drug?  
5 MR. RAKOCZY: We have an expert economist,  
6 Your Honor, who specializes in analyzing how pharmaceutical  
7 products fare in the market, and our view is, this type of  
8 testimony is, in fact, expert testimony, and the purview --  
9 THE COURT: That's not the question I asked you,  
10 is it? Please be responsive to what I put to you.  
11 I said, are you challenging the commercial success  
12 of Prezista?  
13 MR. RAKOCZY: Absolutely we are, Your Honor, yes.  
14 THE COURT: You are?  
15 MR. RAKOCZY: Yes.  
16 THE COURT: All right. I'll permit it, then. All  
17 right. That takes care of that.  
18 Q. So how is it doing in the marketplace?  
19 A. Well, today, last year, we had close to a million  
20 prescriptions of Prezista.  
21 Q. That's Exhibit 910. It's a summary slide. How have  
22 they grown over the years?  
23 MR. RAKOCZY: Objection, Your Honor, if I may.  
24 THE COURT: Yes. Yes, sir.  
25 MR. RAKOCZY: Your Honor, we are challenging

118

1 MR. RAKOCZY: Your Honor, that whole idea, 70 to  
2 80 percent, that is expert opinion. That is not a lay  
3 opinion if someone walks up the street --

4 THE COURT: That is why I was going to it, good  
5 friend. Trust me sometimes. All right?

6 (Laughter)

7 MR. RAKOCZY: Thank you, Judge.

8 BY MR. DISKANT:

9 Q. In any event, in your view, what effect would losing  
10 these patent cases have --

11 THE COURT: No, I think you ought to finish. All  
12 right?

13 MR. DISKANT: Okay. In that case, I'll ask one  
14 last round of questions.

15 Q. We talked about enforcing patents here in the U.S.  
16 Does J & J have a different policy with respect to  
17 sub-Saharan Africa and the least developed countries?

18 A. Yes, it does.

19 MR. RAKOCZY: Objection, Your Honor.

20 THE COURT: I want to ask you about a movie, did  
21 you see it, "A Bridge Too Far"?

22 (Laughter)

23 THE COURT: All right. That's it. We shall now  
24 recess for lunch. We'll see you at two o'clock.

25 (Luncheon recess taken)

**CHARLES P. McGUIRE, C.C.R.**

120

1 slides, if we could.

2 MR. RAKOCZY: Could we please call back up  
3 Stoffels 9?

4 Q. And I believe, Dr. Stoffels, this is your depiction of  
5 the HIV life cycle you testified about; is that correct?

6 A. Yes.

7 Q. And if we look on this Stoffels 9 demonstrative,  
8 there's an error at the bottom, it says protease inhibitor;  
9 correct?

10 A. Correct, yes.

11 Q. So the protease is actually inside the cell; correct?

12 A. Protease enzyme is inside the cell, yes.

13 Q. So this whole mechanism of inhibiting protease, that  
14 occurs intracellularly, correct?

15 A. That occurs intracellular to the formation of the  
16 virus, yes.

17 Q. All right. Now, let's turn to your next  
18 demonstrative, Stoffels 10, and this was a depiction where  
19 you are depicting a pair of scissors as the protease;  
20 correct?

21 A. I am doing that simplification, yes.

22 Q. And then in Stoffels 11, you are depicting the  
23 protease inhibitor as it looks like a red pin that prevents  
24 the scissors from closing; is that correct?

25 A. It's a depiction. Yes.

**CHARLES P. McGUIRE, C.C.R.**

119

AFTERNOON SESSION

1 THE COURT CLERK: All rise.

2 THE COURT: Good afternoon again.

3 Where is our witness?

4 Okay.

5 You may be seated.

6 (The witness resumed the stand.)

7 MR. RAKOCZY: Good afternoon, Your Honor.

8 THE COURT: Are you finished direct examination?

9 MR. DISKANT: Yes, Your Honor.

10 THE COURT: All right. Yes, sir.

11 MR. RAKOCZY: Good afternoon, Your Honor.

12 William Rakoczy for the Lupin and Mylan Defendants.

13 Good afternoon, Dr. Stoffels.

14 Excuse me, Your Honor. May I proceed?

15 THE COURT: Yes. We're waiting for you.

16 MR. RAKOCZY: Thank you.

17 CROSS-EXAMINATION

18 BY MR. RAKOCZY:

19 Q. Afternoon, Dr. Stoffels.

20 A. Good afternoon.

21 Q. We haven't met. I represent the Lupin and Mylan  
22 Defendants. I'll have just a few questions for you.

23 A. Nice to meet you.

24 Q. I would like to start with some of your demonstrative

121

1 Q. All right. Now, my question is, if that red pin is a  
2 protease inhibitor, and in particular, if it's Prezista, or  
3 Prezista, excuse me, then that's the actual darunavir  
4 molecule that's inhibiting the protease; correct?

5 A. I just wanted to demonstrate how a protease inhibitor  
6 could be blocked depicted by the scissor and a nail, yes.

7 Q. So if that was Prezista, that would be the darunavir  
8 molecule that's blocking the protease; correct?

9 A. That's a depiction of that, yes.

10 Q. That is not depicting the ethanolate or the  
11 ethanolate; correct?

12 A. I am not the expert to say that, the relationship  
13 between -- this is -- I can't say that.

14 Q. So you think that that inhibitor inside the cell could  
15 be the ethanolate, the actual ethanol inside the cell  
16 inhibiting protease?

17 A. I'm not the expert to say that.

18 Q. So you don't know one way or another what is actually  
19 inhibiting the protease.

20 A. I know it's a chemical molecule, which is synthesized  
21 and which is -- which is synthesized as an ethanolate, which  
22 absorbs in the body. How it's then getting metabolized and  
23 gets into the cell, I am not the expert to describe that to  
24 you.

25 Q. Well, once the patient ingests Prezista, the drug

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