

1 IN THE UNITED STATES DISTRICT COURT  
2 IN AND FOR THE DISTRICT OF DELAWARE

3 NOVARTIS PHARMACEUTICALS : CIVIL ACTION  
4 CORPORATION, NOVARTIS :  
5 AG, NOVARTIS PHARMA AG, :  
6 NOVARTIS INTERNATIONAL : - VOLUME C -  
7 PHARMACEUTICALS LTD, and :  
8 LTS LOHMANN :  
9 THERAPIE-SYSTEME AG, :  
10 Plaintiffs, :

11 vs. :

12 PAR PHARMACEUTICAL, :  
13 INC., : NO. 11-1077-RGA  
14 Defendant. : CONSOLIDATED

15 ----- : CIVIL ACTION

16 NOVARTIS PHARMACEUTICALS :  
17 CORPORATION, NOVARTIS :  
18 AG, NOVARTIS PHARMA AG, :  
19 NOVARTIS INTERNATIONAL :  
20 PHARMACEUTICALS LTD, and :  
21 LTS LOHMANN :  
22 THERAPIE-SYSTEME AG, :  
23 Plaintiffs :

24 vs. :

25 WATSON LABORATORIES, :  
26 INC., WATSON PHARMA, :  
27 INC., and WATSON :  
28 PHARMACEUTICALS, INC., : NO. 11-1112-RGA  
29 Defendants.

30 Wilmington, Delaware  
31 Wednesday, August 28, 2013  
32 8:33 o'clock, a.m.

33 - - -

34 BEFORE: HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

35

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1 THE COURT: All right. Shall we  
2 reconvene at 1:30?

3 MR. PRUGO: Terrific idea.

4 MR. FIGG: That's fine.

5 THE COURT: All right. We'll  
6 reconvene at 1:30.

7 (A luncheon recess was taken.)

8 THE COURT: All right. Please be  
9 seated.

10 Are we ready to go?

11 MR. PRUGO: We are, Your Honor.

12 THE COURT: All right. Go ahead,  
13 Mr. Prugo.

14 MR. PRUGO: Plaintiffs next call to  
15 the stand Dr. Tiemessen. He's an inventor on the  
16 patents in suit and is here today to talk about  
17 the development work leading to those patents.

18  
19 Henricus Tiemessen, having been  
20 first duly sworn, was examined and  
21 testified as follows:

22  
23 - - -DIRECT EXAMINATION- - -

24 BY MR. PRUGO:

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1 cooperation between Sandoz and Lohmann was put on  
2 hold. We were waiting for internal decision.

3 On the one hand, we had also the  
4 oral project going on. Those were milestones  
5 that we awaited in order to find out where the  
6 management wants to take the further project.

7 And, on the other hand, also in our  
8 department we had prepared those to think how to  
9 do this production of the free base. So we took  
10 that time because we were still motivated to get  
11 on to prepare plans to put everything together,  
12 plans to do what needs to be done in order to go  
13 on with the project as soon as we get the green  
14 light from management.

15 Q. Okay. If you could turn to Tab 4 in your  
16 witness binder. There you'll find JTX 191.

17 Can you identify that document for  
18 us?

19 A. Yes. That is the technical development  
20 plan, which was prepared early or first half of  
21 1994.

22 Q. And if we could turn specifically to  
23 N0260070.

24 Thank you.

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1                   There's a section five. There we  
2 go.

3                   It's on the screen now. Technical  
4 hurdles. Do you see that?

5           A. Yes.

6           Q. Can you explain to the Court what's  
7 written here?

8           A. This is a table which we have compiled all  
9 the technical hurdles which we could encounter  
10 when we carry out the program. And the first is  
11 the identification of the hurdle. The  
12 probabilities that hurdle actually will occur.

13                   And the third column we have the  
14 impact. If this hurdle occurs, what will be the  
15 impact in terms of time, cost or termination.

16           Q. All right. Thank you.

17                   And I want to just do these one at  
18 time. Here it states stability/quality of base.  
19 What does that mean?

20           A. This refers to the drug substance, the  
21 rivastigmine base. This refers to the stability,  
22 the quality, as well as also the manufacturing of  
23 the base because Sandoz had never produced a drug  
24 substance as a liquid.

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1 Q. And under probability, you see the number  
2 15 percent. What does that indicate?

3 A. That indicates that we go back to  
4 encounter serious problem, problem about -- 15  
5 percent is a very low figure.

6 Q. And can you describe for us what the  
7 impact was?

8 A. Okay. When we would encounter this  
9 problem, then we expect to have a delay in order  
10 to fix this problem.

11 Q. Okay. And the next technical hurdle,  
12 stability of patch.

13 What is that a reference to?

14 A. That's referring to the -- it was the  
15 chemical as well as the physical stability of the  
16 patch. And that also includes the adhesion  
17 properties, et cetera.

18 Q. And can you describe for the Court what  
19 the 20 percent refers to?

20 A. This refers to the total of the  
21 probability that you would have, either chemical  
22 instability or physical instability.

23 Q. Okay. Can you walk us through the  
24 potential impact?

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