

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

-----  
PFIZER INC. and UCB PHARMA GMBH  
Plaintiffs

vs.  
C.V. No. 13-1110 (GMS)

ALKEM LABORATORIES LTD., CONSOLIDATED  
Et al.  
Defendants.

-----  
CONFIDENTIAL ATTORNEYS EYES ONLY  
Videotaped Deposition of Claus Meese  
Vol 1

Taken at the offices of:  
McDermott Will & Emery  
Avenue des Nerviens 9-31  
1040 Brussels

Tuesday, 20th January 2015  
At 9.49 a.m.

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202-220-4158

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

2

3       ON BEHALF OF PLAINTIFFS and THE WITNESS:

4           WHITE & CASE LLP  
5           1155 Avenue of the Americas  
6           New York, New York 10036-2787  
7           212.819.8255  
8           JAMES S. TRAINOR, ESQ.  
9           jtrainor@whitecase.com  
10          JURGEN HASSA  
11          jurgem.hassa@ucb.com  
12          REBECCA McCULLOUGH

13       ON BEHALF OF DEFENDANT, APOTEX, INC.:

14           RAKOCZY MOLINO MAZZOCHI SIWIK LLP  
15           Six West Hubbard Street  
16           Suite 500  
17           Chicago, Illinois 60654  
18           312.527.2157  
19           BY PHONE: ERIN FORBES  
20           eforbes@rmmslegal.com

21       ON BEHALF OF DEFENDANTS, HETERO USA INC. and  
22       HETERO LABS LIMITED:

23           AXINN, VELTROP & HARKRIDER LLP  
24           114 West 47th Street  
25           New York, New York 10036  
26           212.728.2200  
27           BY PHONE: MATT MURPHY ESQ.  
28           mmurphy@axinn.com

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1                   A P P E A R A N C E S (contd)

2

3       ON BEHALF OF DEFENDANTS, SANDOZ INC.

4

5                   McDERMOTT WILL & EMERY  
6                   227 West Monroe Street  
7                   Chicago, Illinois 60606-5096  
8                   312.984.5810  
9                   slo@mwe.com  
10                  WAN-SHON LO

8

9       ON BEHALF OF DEFENDANTS, WOCKHARDT BIO AG and  
10       WOCKHARDT USA, LLC:

10

11                  KNOBBE, MARTENS, OLSON & BEAR, LLP  
12                  2040 Main Street  
13                  14th Floor  
14                  Irvine, California 92614  
15                  949.760.0404  
16                  KAREN CASSIDY, ESQ.  
17                  karen.cassidy@knobbe.com

15

16       Also Present:

17                  Kay Hendrick - Court Reporter

18                  Simon Rutson - Videographer

19                  Andrea Boyer - Interpreter

20

21

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1 Tuesday, 20th January 2015

2

3 THE VIDEOGRAPHER: Good morning, this is  
4 the beginning of Tape One, Volume One in the  
5 deposition of Dr Claus Meese taken on 20th  
6 January 2015 at 9.49 am, as indicated on the video  
7 screen. This deposition is being taken in the  
8 matter of Pfizer Inc. and UCB Pharma GMBH,  
9 Plaintiffs, versus Alkem Laboratories Limited et  
10 al, Defendant's, case number CA13-1110 (GMS)  
11 Consolidated, being heard in the United States  
12 District Court for the District of Delaware.

13 The deposition is taking place at the  
14 offices of McDermott Will & Emey in Brussels,  
15 Belgium.

16 The videographer is Simon Rutson. The  
17 Court Reporter is Kay Hendrick on behalf of  
18 Henderson Legal Services.

19 Would counsel in the room please  
20 introduce themselves and state whom they  
21 represent?

22 MS CASSIDY: Karen Cassidy from Knobbe,  
23 Martens, Olson & Bear representing the Wockhardt  
24 Defendant's.

25 MS LO: Wan-Shon Lo representing the

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1 Defendants Sandoz Inc.

2 MR HASSA: Jurgen Hassa European Patent  
3 Attorney, representing UCB.

4 MR TRAINOR: Jim Trainor from White &  
5 Case in New York on behalf of the Plaintiffs  
6 Pfizer, UCB, also on behalf of the witness. With  
7 me today is my colleague Rebecca McCullough.

8 THE VIDEOGRAPHER: Would counsel  
9 appearing telephonically please introduce  
10 yourselves and state who you represent?

11 MR MURPHY: Matt Murphy on behalf of  
12 Axinn Veltrop & Harkrider on behalf of the Hetero  
13 Defendant's.

14 MS FORBES: Good morning. This is Erin  
15 Forbes from Rakoczy Molino Mazzochi Siwik  
16 representing Apotex Inc.

17 THE VIDEOGRAPHER: Anyone else on the  
18 line?

19  
20 Interpreter affirmed.

21 CLAUS MEESE  
22 having been duly sworn,  
23 testified as follows:

24 Examination by Ms Cassidy:

25 Q. Good morning, Dr Meese. Could you

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1 please state your name and address for the record?

2           **A. My name is Claus Meese and my**  
3 **address is -- my name is Claus Meese, Kreuzberger**  
4 **50, 40748 Monheim, possibly 789 Monheim.**

5           Q. Dr Meese, are you represented by  
6 counsel today?

7           MR TRAINOR: I represent to you that we  
8 are representing the witness if he is confused by  
9 that but ...

10          MS CASSIDY: Dr Meese, have you ever  
11 been deposed before?

12           **A. No, never.**

13          Q. Alright. Are you aware of any  
14 reason you would be unable to give full and  
15 accurate testimony today?

16           **A. No.**

17          Q. So a few ground rules for how we are  
18 going to run this deposition. I will ask you  
19 questions. The Court Reporter is here to take  
20 down the questions and your answers. Please make  
21 sure to give verbal responses so that the Court  
22 Reporter can take down your response and please  
23 wait until the question has been completed before  
24 you answer it?

25           **A. Yes.**

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1 Q. If you do not understand a question  
2 please let me know otherwise I will assume that  
3 you understand?

4 A. Okay.

5 Q. Your attorney may object, please  
6 answer the question unless you are instructed not  
7 to answer by your attorney?

8 A. Okay.

9 Q. And if you need to take a break just  
10 let me know and we can take a break at any time  
11 but if there is a question pending please answer  
12 before we take a break?

13 A. Okay, yes.

14 Q. Did you do anything to prepare for  
15 this deposition?

16 A. We have had some discussions with  
17 our lawyers, and I had a look at previous document  
18 from the patent literature and our own work in  
19 order to recall everything, because some time has  
20 passed since that time.

21 Q. Did you meet with anyone aside from  
22 your attorney to prepare for the deposition?

23 A. No.

24 Q. And did you review any documents  
25 while you were preparing for this deposition?

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1           A. Yes, as I mentioned before the  
2 patent literature and our own documents, the  
3 patent which we have filed in order to recall this  
4 world.

5           Q. We are going to start with a little  
6 bit of your background. Could you please describe  
7 your education history since after high school?

8           A. Yes, I started organic chemistry and  
9 as well as pharmaceutical chemistry and pharmacy  
10 and made my diploma and Doctor of thesis at the  
11 university of Hamburg. And afterwards, do you  
12 want me to tell what I did later on?

13          Q. Yes, actually that was going to be  
14 my next question, so you could explain after you  
15 finished your formal education what your first job  
16 was?

17          A. I have had a job at the University  
18 of Hamburg. I was a so-called assistant for the  
19 advanced chemistry student. And after that time  
20 it changed to the administration authorities of  
21 Hamburg, the Department of Environmental Affairs,  
22 and I specialized on the analytics of water, that  
23 means any kinds of water, tap water and bath  
24 water, swimming and so on. After a time  
25 I changed.

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1           I moved to Stuttgart and used to work in  
2     the Institute of Clinical Pharmacology,  
3     Dr Margarete Fischer-Bosch, that is a private  
4     institution sponsored by the Robert Bosch  
5     Foundation in Stuttgart. And I used to work there  
6     for 14 years and I established a chemistry  
7     department at this Institute and primarily made  
8     studies on drugs, drug metabolism, in-vitro as  
9     well as animal studies, analytics, and after that  
10    time, which ended in 1993, I moved to a  
11    pharmaceutical company, Schwarz Pharma, at that  
12    time in Monheim, Germany, and I was responsible  
13    for the Chemistry Department of this Company.

14           In this Company I was involved in the  
15    development of new drugs and all chemistry affairs  
16    which occur in a pharmaceutical company until  
17    2007. And during that time there was a time where  
18    very many papers were published and patents were  
19    made on different issues. This is well  
20    documented.

21           Q. And after 2007 were you employed  
22    anywhere else or did you retire at that time?

23           A. After 2007 when I left the Company  
24    I retired.

25           Q. Thank you.

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1           A. And the reason was simply that my  
2 Company was merged with UCB Pharma GMBH from  
3 Belgium, and it was clear that many changes would  
4 occur there due to process, so I decided to leave  
5 the Company. It was a smooth goodbye from this  
6 Company, so I said yes. Any more questions?

7           Q. Are you familiar with a compound  
8 called festoterodine fumarate?

9           A. Yes, yes. I can say yes, I know  
10 this compound.

11          Q. Did you work with festoterodine  
12 fumarate anywhere besides your employment at  
13 Schwarz?

14          A. No, never. Never.

15          Q. And do you understand that the  
16 r-enantiomer of the festoterodine fumarate may  
17 also be referred to as SPM 8272?

18          A. Yes, I know that.

19          Q. Okay. And are you familiar with the  
20 festoterodine freebase?

21          A. Yes, I am.

22          Q. Did you work with that anywhere  
23 besides at Schwarz Pharma?

24          A. No, never.

25          Q. And do you understand that the

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1 r-enantiomer of the freebase may also be referred  
2 to as SPM 8224?

3 **A. Yes, it's the freebase. It's**  
4 **freebase. 8272 is the salt.**

5 Q. And are you familiar with a compound  
6 called tolterodine?

7 **A. Yes.**

8 Q. Did you work with tolterodine  
9 anywhere besides in your employment at Schwarz?

10 **A. No, never.**

11 Q. And are you familiar with a compound  
12 called 5-hydroxymethyl tolterodine?

13 **A. Yes.**

14 Q. And are you comfortable if we refer  
15 to this as 5-HMT throughout the deposition, will  
16 you understand what I am referring to?

17 **A. Yes.**

18 Q. And did you work with 5-HMT anywhere  
19 besides in your employment at Schwarz?

20 **A. No, never.**

21 Q. How many patents are you listed as  
22 an inventor on?

23 **A. I only remember the major patents,**  
24 **the priority patent which was filed in May 1998**  
25 **the first one. And I remember, please correct me**

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1 if I am wrong, in total six patents. Yeah.

2 Q. And the six patents that you are  
3 referring to, are these all related to derivatives  
4 of the 5-HMT metabolite?

5 MR TRAINOR: Objection.

6 A. Yes.

7 MS CASSIDY: I am going to hand you a  
8 document which will be marked as Meese Exhibit 1,  
9 and it bears Bates numbers PT 00000001 through PT  
10 00000019.

11 (Exhibit 1 marked for identification)

12 A. Yes, okay. Thank you.

13 Q. Dr Meese, do you recognize this  
14 document?

15 A. Yes.

16 Q. And can you tell me what this  
17 document is?

18 A. It describes new salt, stable salt  
19 and suitable salt, often metabolite they are  
20 talking of.

21 Q. And this document is a patent  
22 bearing the number US 6858650; is that correct?

23 A. That is right.

24 Q. Dr Meese, you are named as a sole  
25 inventor on this patent?

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1 "From document PCT/EP 99/03212 novel  
2 derivatives of 3,3-dipenylpropylamine. These are  
3 valuable prodrugs for the treatment of urinary  
4 incontinence and other spasmodics complaints which  
5 overcome the disadvantage of the active substances  
6 available to date, namely inadequate absorption of  
7 the active substance by biological membranes or  
8 the unfavorable metabolism of these."?

9 **A. Yes.**

10 MS CASSIDY: Dr Meese, did you help  
11 draft that paragraph?

12 MR TRAINOR: If you remember.

13 **A. Most primarily, as far as I remember**  
14 **written by the Patent Department people and the**  
15 **pharmacologists which gave some advice, because**  
16 **I just want to recall I am a chemist, and this is**  
17 **my focus on the whole issue.**

18 MS CASSIDY: And do you recall the time  
19 this was drafted do you agree with the statement  
20 that essentially the derivatives of the  
21 3,3-dipenylpropylamines were known?

22 **A. Derivatives were known since the**  
23 **1960s.**

24 MS CASSIDY: And do you recall who the  
25 pharmacologists who assisted in the drafting of

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1 this patent were?

2 MR TRAINOR: Objection.

3 A. I can't say the name but it must be  
4 a pharmacologist from the project team.

5 MS CASSIDY: Now, if you will look at  
6 column one, starting at line 63 through column one  
7 or column two, line 3 where it says:

8 "Surprisingly, it has now been found  
9 that the above mentioned disadvantages can be  
10 avoided if compounds with a structure of general  
11 formula A once they have been prepared under a  
12 special reaction process are converted with a  
13 physiologically compatible inorganic or organic  
14 acid with the general formula HX in which X  
15 represents the respective acid residue into their  
16 respective salt with the general formula I."?

17 A. Yes.

18 MS CASSIDY: If I could direct your  
19 attention to figure one of the 650 patent, I  
20 believe it will be one page over on your copy,  
21 back towards the front of the document?

22 A. Yes.

23 MS CASSIDY: Is the reaction depicted in  
24 figure one the special reaction process that was  
25 referred to in the section from column one of the

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1 patent that we just read?

2 MR TRAINOR: Objection.

3 A. Yes, it's a abbreviated depiction of  
4 the transition from 1 to 2.

5 MS CASSIDY: And for this abbreviated  
6 figure why were these particular steps selected  
7 for the abbreviated figure 1?

8 A. Just to give an overview how we got  
9 compound 6 from 3 and then following steps from 3  
10 to 2A or 2B they are essential, and they are again  
11 shown in the following columns.

12 MS CASSIDY: When you say that these  
13 steps are essential, do you recall whether in the  
14 full synthesis there are other essential steps as  
15 well?

16 MR TRAINOR: Objection.

17 A. Yes, certainly. The Regio specific  
18 acylation giving a compound of the formula A is  
19 certainly a crucial step, and salt formation again  
20 is a crucial step formula. We have 1, yes, on  
21 column 2.

22 MR TRAINOR: That is "R-E-G-I-O  
23 selective".

24 A. Yes, Regio selective because the  
25 precursor compound Number 6 in figure 1 has two

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1 hydroxy groups and really it was to our experience  
2 surprising that only the phenolic hydroxy groups  
3 react under certain conditions with the respective  
4 acylation agent.

5 MR TRAINOR: That is A-C-Y-L-A-T-I-O-N.  
6 I am just helping her.

7 MS CASSIDY: Why was it surprising that  
8 only the phenolic hydroxy groups reacted under  
9 certain conditions?

10 A. We didn't expect that before,  
11 because there are two hydroxy groups available and  
12 molecule and we didn't expect a high degree of  
13 specificity.

14 MS CASSIDY: Was this because you  
15 expected both hydroxy groups to be equally  
16 reactive?

17 A. Yes, or less or more, but this way.

18 Q. I am going to hand you a document  
19 that has been previously marked as Sparf  
20 Exhibit 11 and it is bearing Bates numbers PT  
21 00000020 through PT 00000052. Actually I think we  
22 are going to mark that, if you hand that back to  
23 the Court Reporter. We will mark this as Meese  
24 Exhibit 2.

25 (Exhibit 2 marked for identification)

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1 Dr Meese, if you can take a minute to  
2 look at this document and let me know if you  
3 recognize it?

4 A. Yes.

5 Q. Dr Meese, what is this document that  
6 I have handed you?

7 A. A document the American translation  
8 of our priority patent from May 12th 1998.

9 Q. And this bears US patent Number  
10 7384980; is that correct?

11 A. This paper here, yes.

12 Q. Yes?

13 A. 980.

14 Q. And you are listed as a co-inventor  
15 with Bengt Sparf; is that correct?

16 A. That is correct.

17 Q. And who is Bengt Sparf?

18 A. Bengt Sparf is a pharmacologist from  
19 Sweden who was familiar with anti-muscarinic drugs  
20 for many years and at that time he was kind of  
21 consultant for Schwarz Pharma, because this -- no,  
22 no.

23 Q. Do you recall how Dr Sparf became  
24 involved in this project, in this patent?

25 MR TRAINOR: Objection.

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1           A. Well, we researched CEO of Schwarz  
2 Pharma, we needed external input. At that time  
3 the whole project was initiated at Schwarz Pharma,  
4 so this expert was willing to give support.

5           MS CASSIDY: Do you recall whether you  
6 had started work on this project prior to Dr Sparf  
7 becoming involved?

8           A. No, we haven't done anything on this  
9 field before.

10          MS CASSIDY: What do you understand  
11 Dr Sparf's contribution to the invention described  
12 in the 980 patent to be?

13          MR TRAINOR: Objection.

14          A. Well, his contribution was primarily  
15 in the field of pharmacology and handling of  
16 anti-muscarinic drugs in human and animal studies.  
17 There was no contribution in the field of  
18 chemistry, no significant contribution.

19          MS CASSIDY: And what do you understand  
20 your contribution to the invention described in  
21 this patent to have been?

22          MR TRAINOR: Objection.

23          A. I was responsible for the chemistry,  
24 for all chemical aspects.

25          MS CASSIDY: What do you understand the

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1 difference between the 650 patent, the inventions  
2 described in the 650 patent and the invention in  
3 the 980 patent to have been?

4 MR TRAINOR: Objection.

5 A. 650 patent, this and this one?

6 MS CASSIDY: Yes.

7 A. The focus in the 650 patent clearly  
8 was on the formation of stable salts, as the title  
9 says. And the 980 is a more general patent on  
10 many more aspects of drug development.

11 Q. I am going to hand you a document  
12 which will be marked as Meese Exhibit 3, bearing  
13 Bates numbers PT 00000053 through PT 00000085.

14 (Exhibit 3 marked for identification)

15 A. Does that mean we are done with  
16 these for now?

17 Q. You can set them aside for now, we  
18 may come back to them. Do you recognize this  
19 document, Dr Meese?

20 A. Give me a second, yes. Okay.

21 Q. Do you recognize this document?

22 A. Yes.

23 Q. And if you look in the top right  
24 corner this document is bearing the US patent  
25 number 7855230; is that correct?

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1                   **A. Yes.**

2                   Q. And you and Dr Sparf are named as  
3 co-inventors on this patent, correct?

4                   **A. Yes.**

5                   Q. And if you could please turn to the  
6 last page, the page ending in Bates Number 085  
7 with the column top 56?

8                   MR TRAINOR: The last page or column 56?

9                   MS CASSIDY: Column 56 which should be  
10 on the last page.

11                  MR TRAINOR: 57, 58 -- sorry, I have the  
12 wrong Exhibit. I apologize.

13                  **A. Column 56 and which number there?**

14                  THE INTERPRETER: Which line number?

15                  MS CASSIDY: Starting at line number 17  
16 right after it says "The invention claimed is,"  
17 then the Number 1?

18                  **A. Yeah.**

19                  MS CASSIDY: And looking at Claim 1 what  
20 do you understand the difference between the 230  
21 patent and the 980 patent, Exhibit 2, that we were  
22 just looking at to be?

23                  MR TRAINOR: Objection. If you have an  
24 understanding.

25                  **A. Yeah. There is a clear difference**

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1 because the focus of this claim is clearly the  
2 transdermal application of the novel derivatives,  
3 and that was absolutely new and nobody thought of  
4 that before. Not oral, but transdermal.

5 MS CASSIDY: And what was your  
6 contribution to the invention described in this  
7 patent?

8 MR TRAINOR: Objection.

9 A. Simply spoken nobody thought of this  
10 transdermal application of this kind of normal  
11 compounds. Never before. And I was convinced  
12 that transdermal application has considerable  
13 advantages over oral, orally administered drug.

14 MS CASSIDY: Okay. I am handing you a  
15 document that will be marked as Meese Exhibit 4.  
16 It is a document bearing Bates numbers PT 00000086  
17 through PT 00000117.

18 (Exhibit 4 marked for identification)

19 Do you recognize this document,  
20 Dr Meese?

21 A. Sorry. Yes, I remember it.

22 Q. And do you understand this document  
23 to be a patent bearing the US patent Number  
24 7985772?

25 A. Yes.

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1 Q. You are a co-inventor on this patent  
2 with Dr Sparf; is that correct?

3 A. Yes.

4 Q. And what do you understand your  
5 contribution to this, to the invention in this  
6 patent to have been?

7 MR TRAINOR: Objection. I just object  
8 to this whole line of questioning. These are  
9 about questions of law. This man is here to  
10 answer questions about facts. Interpreting patent  
11 documents, understanding what claims mean, what  
12 the difference between what one document is and  
13 another, legal documents, examine as you wish but  
14 I object to this question.

15 A. I just want to emphasise my initial  
16 command that I was responsible for the chemistry  
17 and not for other aspects.

18 MS CASSIDY: Okay. And based on your  
19 recollection do you understand -- what is your  
20 understanding is the difference between the 772  
21 patent and the 230 patent that we just discussed?

22 MR TRAINOR: Objection.

23 A. There is one big difference. It's  
24 column 53 -- I go back again. Sorry. Sorry, but  
25 it's a couple of years ago so I have to.

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1 MR TRAINOR: Can we give him the  
2 question back and can you please translate it?

3 MS CASSIDY: Before you do, Dr Meese,  
4 I can clarify, this is just based on your  
5 recollection, if you recall what the difference  
6 was?

7 A. First I see novel derivatives  
8 prepared by other methods, some experiments make  
9 polymers loaded with active drug. I can't find it  
10 now but I know there was a section for benzylic  
11 esters.

12 Q. Dr Meese, this is just based on your  
13 recollection. I understand it has been some time  
14 since you have looked at this, you don't need to  
15 analyze the entire document if you don't want to,  
16 based on your recollection what you have told us  
17 should be sufficient?

18 A. Okay. I just remember novel methods  
19 and novel variance, and one of them, an enzymatic  
20 process to get the benzylic esters which could not  
21 be obtained by other methods. It was completely  
22 new, and that's what I remember right now.

23 Q. Dr Meese, I am handing you a  
24 document bearing -- marked as Exhibit Number 5  
25 bearing Bates numbers PT 00000118 through PT

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1 00000149.

2 (Exhibit 5 marked for identification)

3 Dr Meese, do you recognize this  
4 document?

5 A. I will have to have a look at it  
6 first. Sorry. Yes.

7 Q. And do you recognize this document  
8 to be a US patent bearing patent Number 8338478?

9 A. Yes.

10 Q. And you are listed as co-inventor on  
11 this patent along with Dr Sparf; is that correct?

12 A. Yes.

13 Q. And if you recall what was your  
14 contribution to this patent?

15 MR TRAINOR: Objection. Talking about  
16 the patent, the claims?

17 MS CASSIDY: Sorry, to the invention  
18 disclosed in this patent?

19 A. Well, basically the processes, and  
20 I mean the chemical processes necessary to make  
21 novel derivatives but -- and I want to emphasise  
22 this, only until 2012, after that it was no longer  
23 Schwarz but UCB that was updating them.

24 Q. Dr Meese, do you receive any  
25 benefit, do employees at Schwarz receive any

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1 benefit for being named as inventors on patents?

2 **A. Not in financial terms, no. It is**  
3 **appreciated but that's all.**

4 Q. I am going to hand you a document  
5 which bears the Bates number -- we will be marking  
6 as Meese Exhibit 6 bearing Bates numbers PT --  
7 sorry, Exhibit 6?

8 MR TRAINOR: Five?

9 MS CASSIDY: Six. Exhibit 6 bearing the  
10 Bates numbers PT 02019287 through PT 02019292.

11 (Exhibit 6 marked for identification)

12 I am also handing you an English, a  
13 certified English translation of the same document  
14 which we will be marking as Meese Exhibit 7.

15 (Exhibit 7 marked for identification)

16 **A. But this is not a copy for me,**  
17 **right, this is part of the document. I have never**  
18 **seen this translation before.**

19 Q. This translation is one that we  
20 made. It is a copy that was translated of the  
21 German version so that we could understand what  
22 the document said?

23 **A. Okay. I never have seen it, yeah.**

24 Q. Dr Meese, if I could direct your  
25 attention to Exhibit 6, the German version of this

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1 document?

2 **A. Yes.**

3 Q. If you could please take a look at  
4 this and let me know if you recognize the  
5 document?

6 **A. Well, yes, I signed it.**

7 Q. And this is an agreement relating to  
8 an inventor's bonus; is that correct?

9 **A. Yes.**

10 Q. If you could please turn to page 2  
11 of the agreement. And if you look at Section 1  
12 relating to international patent application  
13 W099/58478?

14 **A. Where exactly is that.**

15 Q. If you look on page 2 there is a  
16 bold 1 and underneath it a non bold 1?

17 **A. Okay.**

18 Q. Underneath unbolded 1 is where you  
19 will see International Patent Application  
20 W099/58478?

21 **A. Yes.**

22 Q. And underneath that do you see that  
23 there is a line labeled "inventors" with your name  
24 and Dr Sparf's name?

25 **A. Yes.**

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1 Q. And next to your name is an 80%?

2 A. Yes.

3 Q. Do you have any recollection as to  
4 what the 80% represents?

5 MR TRAINOR: Objection.

6 A. That's what the two inventors agreed  
7 to.

8 MS CASSIDY: And when you say it is what  
9 the two inventors agreed to, do you mean agreed to  
10 as in a representation of their share of the work?

11 MR TRAINOR: Objection.

12 A. Yes.

13 MS CASSIDY: Okay. And if you could  
14 turn to page 4 of the agreement which has in the  
15 bottom right corner a Bates number PT 02019290.

16 A. Yes.

17 Q. And if you look at the paragraph  
18 with the bold number 5 next to it, it should be  
19 the last paragraph on the page?

20 A. Yes.

21 Q. And in this paragraph Schwarz Pharma  
22 agreed to pay you a one time flat rate inventor's  
23 bonus in the amount of 1m Euros; is that correct?

24 A. Yes.

25 Q. And if you turn to the next page,

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1 looking next to the paragraph with the bold  
2 Number 6 next to it, Schwarz Pharma also agreed to  
3 pay an additional flat rate bonus in the amount of  
4 200,000 Euros per year from March 31st 2007 until  
5 2016; is that correct?

6 **A. Yes.**

7 Q. And you previously testified that  
8 Schwarz normally does not pay bonuses for being  
9 named as an inventor on their patent?

10 **A. This is not a bonus. No, this is**  
11 **not considered a bonus. This is an obligation**  
12 **under the German law which protects inventors.**

13 MR TRAINOR: For the record I would like  
14 to designate the entire transcript highly  
15 confidential pursuant to the terms of the  
16 Protective Order.

17 COURT REPORTER: Was yesterday's  
18 confidential as well?

19 MR TRAINOR: For the record yes and we  
20 will make that clear between the parties  
21 off-the-record.

22 MS CASSIDY: Aside from payments under  
23 this contract are you currently receiving any  
24 other payments from Schwarz?

25 **A. My company pension.**

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1 Q. Okay. And are you receiving any  
2 payment from Pfizer at this time?

3 A. No, none.

4 Q. Are you receiving any payments from  
5 UCB?

6 A. Well, yes, to the extent that UCB is  
7 the successor of what was Schwarz Pharma and that  
8 would then again be my company pension.

9 Q. Dr Meese, are you being paid for  
10 your time here today?

11 A. No.

12 Q. We have been going about a little  
13 over an hour, so is this a good time to take a  
14 break?

15 MR TRAINOR: Yes, please.

16 A. Yes, that would be okay.

17 THE VIDEOGRAPHER: Going off-the-record  
18 at 11.06.

19 (Short Recess)

20 THE VIDEOGRAPHER: This is the beginning  
21 of Tape Two, Volume One and a continuation in the  
22 deposition of Dr Claus Meese. On the record at  
23 11.24.

24 MS CASSIDY: Dr Meese, I am going to  
25 hand you a document that will be marked as Meese

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1 Exhibit 8, bearing Bates numbers PT 02075767  
2 through PT 02075771.

3 (Exhibit 8 marked for identification)

4 Dr Meese, if you could take a minute and  
5 review this document and then once you have  
6 finished reviewing please let me know if you  
7 recognize it?

8 **A. There is a blank page in here.**

9 Q. Yes, there should be a blank page in  
10 there?

11 **A. Okay.**

12 MR TRAINOR: The question is do you  
13 recognize this?

14 **A. Yes.**

15 MS CASSIDY: Did you participate in the  
16 drafting of this document?

17 **A. Yes, each member of the early team**  
18 **meetings gave always a sheet of paper to the**  
19 **project manager with some brief notes about the**  
20 **contribution which are planned for the team**  
21 **meetings.**

22 Q. And if I can direct your attention  
23 to the very first line of the chart on the  
24 left-hand column in the column labeled date?

25 **A. Are you referring to the first line?**

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1 Q. Yes, do you see where it says CW 34?

2 A. I wasn't part of that. It is Lars  
3 Ekman and Peter Ney here. I am not a member of  
4 this meeting, of this first meeting.

5 Q. Okay. Do you have any understanding  
6 what CW 34 stands for?

7 A. Calendar week.

8 Q. Do you see under events and topics  
9 in the first line where it says:

10 "Discussion of research proposal on  
11 prodrug of tolterodine metabolite DD 01 made by  
12 BS."?

13 A. Yes, that was the meeting that  
14 I didn't attend, as I said.

15 Q. Although you didn't attend the  
16 meeting did you ever see the letter from Dr Sparf  
17 that's referenced in this event topic?

18 A. I can't see that.

19 Q. If you move to the second line dated  
20 August 28th, 1997?

21 A. Yes.

22 Q. In the sectioned labeled  
23 participants/author does COM refer to you?

24 A. Yes.

25 Q. In this August 28th 1997 meeting was

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1 this the initial project discussion, the very  
2 first project discussion that you were involved  
3 in?

4 **A. Exactly.**

5 Q. And who are the others in attendance  
6 at this meeting?

7 **A. Primarily Bengt Sparf and for a few  
8 couple of minutes at the beginning Peter Ney.**

9 Q. I am going to hand you another set  
10 of two documents but if you could keep this chart  
11 off to the side we will likely be referring back  
12 to it again?

13 **A. Umm hmm.**

14 Q. I am going to be handing you a  
15 document bearing Bates, marked as Meese Exhibit 8  
16 Bates numbers PT -- marked as Meese Exhibit 9,  
17 bearing Bates numbers PT 01855861.

18 (Exhibit 9 marked for identification)

19 And also I am handing you what has been  
20 marked as Exhibit 10 which is an English  
21 translation of PT 01855861.

22 (Exhibit 10 marked for identification)

23 MR TRAINOR: The English translation of  
24 the Exhibit?

25 MS CASSIDY: Of Exhibit 9. I am also

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1 going to be handing you a document marked as  
2 Exhibit 11 bearing Bates numbers PT 01856445.  
3 through PT 01856447

4 (Exhibit 11 marked for identification)

5 THE INTERPRETER: Dr Meese, is asking in  
6 the English translation what does SCL mean?

7 **A. Yes, it is a typing error, it should**  
8 **be SIL which was the name of our chemistry**  
9 **department at the time.**

10 MS CASSIDY: Thank you. I was actually  
11 going to be asking you what SCL stood for?

12 **A. Now it's clear. Thank you.**

13 MS CASSIDY: I am also going to hand you  
14 a document marked as Meese Exhibit 12 which is the  
15 English translation of pages PT 01856445 of  
16 Exhibit 11.

17 (Exhibit 12 marked for identification)

18 THE INTERPRETER: There is mistakes in  
19 this too but I guess it is because it was  
20 translated from a handwritten document where it  
21 case grams and that should be milligrams.

22 MR TRAINOR: If we could wait until she  
23 asks a question.

24 MS CASSIDY: If you could start by  
25 looking at Exhibit 11, and Dr Meese you can refer

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1 to the German version.

2 **A. Yes.**

3 Q. If you look in the top left-hand  
4 corner do you see the date?

5 **A. Yes, of the first meeting on the  
6 topic or brainstorming.**

7 Q. And this was that first meeting we  
8 were discussing in Exhibit 8, the chart?

9 **A. Yes.**

10 Q. And was this the first time that you  
11 had met with Dr Sparf?

12 **A. Exactly.**

13 Q. And during this meeting you have a  
14 note regarding P4502D6, do you recall what that  
15 refers to?

16 **A. It means the formation of the  
17 metabolite if catalyzed by a cytochrome P450 type  
18 2D6 enzyme and generically polymorph. That means  
19 a few percent of the population do not have this  
20 enzyme and this is always in the focus of the  
21 pharmacologist because a new drug which is  
22 metabolized by cytochrome P450 2D6 cannot  
23 metabolize via this polymorphic cytochrome enzyme,  
24 that means the new drug does not form the  
25 respective metabolite.**

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1 Q. And right underneath the reference  
2 to P450 2D6 references the hydroxy metabolite, is  
3 this a reference to 5-HMT?

4 A. Yes.

5 Q. Was this the first time that you had  
6 heard the term that you had been introduced to the  
7 hydroxy metabolite?

8 A. Yes, exactly.

9 Q. Did Dr Sparf provide you with any  
10 written information during this meeting?

11 A. No, no. No. He informed me about  
12 the previous publications and congress reports,  
13 abstracts on this issue, and then we looked at the  
14 literature, patent literature and scientific  
15 literature and found indeed a couple of  
16 disclosures.

17 Q. When you say you found a couple of  
18 disclosures, do you recall what those disclosures  
19 were related to?

20 MR TRAINOR: Objection.

21 A. In very general terms metabolization  
22 of tolterodine.

23 MS CASSIDY: In the left-hand column,  
24 the handwriting towards the top where it says:

25 "Only 10% bioavailability."

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1 Do you recall is that referring to the  
2 bioavailability of the 5-HMT metabolite?

3 A. I don't know. I don't recall right  
4 now. It could be but, no, I really don't want to  
5 speculate.

6 MS CASSIDY: Would that information have  
7 been provided during this meeting by Dr Sparf?

8 MR TRAINOR: Objection.

9 A. Again I would have to speculate.  
10 I can't say.

11 MS CASSIDY: And do you see underneath  
12 the chemical drawings there is a line that says:

13 "(N+) tolterodine: Is now being  
14 licensed." Underneath that "(tartrate) (R)!?"  
15 exclamation point question mark."?

16 A. Umm hmm.

17 MS CASSIDY: Do you recall was that the  
18 form of tolterodine that was being sold on the  
19 market?

20 MR TRAINOR: Objection. Is your  
21 question whether it was sold on the market at that  
22 time or was --

23 MS CASSIDY: At that time?

24 MR TRAINOR: Same objection.

25 A. All I can see is this question mark.

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1 MS CASSIDY: Would the r-enantiomer of  
2 tolterodine metabolize into the r-enantiomer of  
3 the active metabolite?

4 MR TRAINOR: Objection. Did he answer  
5 and you didn't get it.

6 THE INTERPRETER: There has been no  
7 answer.

8 MR TRAINOR: You can answer.

9 THE INTERPRETER: The first part in  
10 German was R is the absolute configuration for  
11 both the parent drug and the metabolite. Then you  
12 added in English.

13 **A. It doesn't change during**  
14 **metabolization.**

15 MS CASSIDY: Did the note that  
16 tolterodine may be licensed in the r-enantiomer  
17 form suggest anything to you in 1997 about the  
18 form a prodrug salt, a prodrug of the active  
19 metabolite salt should take when you developed  
20 your prodrug?

21 MR TRAINOR: Objection.

22 **A. No, at the time I had no documents**  
23 **whatsoever concerning how it would be licensed.**  
24 **That was still Pharmacia back then.**

25 MS CASSIDY: If you could turn now to

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1 Exhibit 9. Do you recognize this document?

2 A. Yes.

3 MS CASSIDY: Is that your handwriting?

4 A. Yes.

5 MS CASSIDY: And do you see where it is  
6 dated 28th August 1997, is this a summary of your  
7 understanding of the August 28th, 1997 meeting?

8 A. Yes, exactly.

9 MR TRAINOR: I just object, there  
10 appears to be more than one date on this document,  
11 so ...

12 MS CASSIDY: I will clarify that for the  
13 record.

14 A. This was one month after the  
15 original first meeting.

16 MS CASSIDY: Okay. Dr Meese, if I could  
17 direct your attention up into the top left-hand  
18 corner, there is a date of September 26th, 2000,  
19 do you see that?

20 A. Well, yes, one month after the first  
21 meeting as far as I can tell. I can't see it  
22 here. It is missing here. It should be here.

23 Q. And your first meeting occurred on  
24 August 28th, 1997, correct?

25 A. Yes, that's right.

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1 Q. Okay?

2 A. Oh, and this is 2000. I don't  
3 remember that.

4 Q. Based on the date of September 26th,  
5 2000 in the top right-hand corner, does this  
6 appear to be a summary of your understanding of  
7 the August 28th, 1997 meeting as you recalled it  
8 on September 26th, 2000?

9 A. Yes, that is what it looks like.

10 Q. And during that August 28th, 1997  
11 meeting Dr Sparf had suggested developing a  
12 prodrug form of the active metabolite; is that  
13 correct?

14 A. Umm hmm. Yes. Yes.

15 Q. And it was your understanding in  
16 1997 that the active metabolite DD 01 had already  
17 been described in the literature as being  
18 biologically active?

19 A. Yes, there is several publications  
20 on that.

21 Q. Prior to your work on the  
22 development of festoterodine had you ever been  
23 involved in the development of a prodrug before?

24 A. No.

25 Q. Do you recall whether prodrugs of

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1 active metabolites were being developed regularly  
2 in 1997?

3 MR TRAINOR: Objection.

4 A. No.

5 MS CASSIDY: You noted that the  
6 suggestion of derivatization of the benzylic  
7 hydroxy group, do you recall why derivatization of  
8 the benzyl active group was suggested first?

9 A. Yes, there are early reports from  
10 the Karolinska institute and some people from  
11 Pharmacia that for the anti-muscarinic  
12 specificity, specificity of similar drugs, the  
13 phenolic hydroxy group has to be free, it must not  
14 be blocked by derivatization. There are several  
15 reports in the patent literature and abstracts  
16 from congresses. It was advised phenolic hydroxy  
17 group has to be free to elicit this  
18 anti-muscarinic activity.

19 MR TRAINOR: I think there was  
20 "advised", not it was a bias. It was advised.

21 A. Exactly.

22 MS CASSIDY: Did Dr Sparf provide you  
23 with that information?

24 A. Yes, but I found it at the same time  
25 by a literature search. It is freely available

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1 for everybody, but he knew these publications, was  
2 clear that phenolic hydroxy group has to be free  
3 to be effective.

4 MS CASSIDY: So if you perform the  
5 derivatization at the phenolic hydroxy group you  
6 would expect the compound to be inactive?

7 MR TRAINOR: Objection.

8 A. That was the belief back then.

9 MS CASSIDY: Could you please turn back  
10 to Exhibit 8?

11 A. Yeah.

12 Q. And if you look at the third row  
13 dated September 19th, 1997?

14 A. Yes.

15 Q. Do you see the events first team  
16 meeting?

17 A. Yes.

18 Q. Do you recall what, if anything,  
19 occurred between the August 28th, 1997 initial  
20 discussion and the first team meeting on  
21 September 19th, 1997?

22 A. The whole chemistry was started.

23 Q. When you say the whole chemistry was  
24 started, what do you mean?

25 A. Everything which is necessary to

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1 initiate a project. We ordered the chemicals. We  
2 completed the literature and references and patent  
3 literature and we started to prepare precursors in  
4 order to get the necessary steps ready.

5 Q. During that time period between  
6 August 28th, 1997 and September 19th, 1997 would  
7 you also have begun drafting potential syntheses  
8 for --

9 A. Not me, it was somebody else.

10 Q. Do you recall who was drafting the  
11 potential syntheses of 5-HMT?

12 A. No, I found here under major points  
13 and decisions it was proposed that Bengt Sparf  
14 write a draft.

15 Q. So is your recollection that  
16 Dr Sparf prepared the first draft of potential  
17 synthesize of the 5-HMT metabolite?

18 A. No, that was not what I meant. It  
19 was his job to draft a mock patent.

20 Q. Okay. If you look under the row  
21 dated August 28th, 1997 under major points and  
22 decisions, that second row, the last sentence  
23 says: "COM to prepare first development plan."?

24 A. Yes.

25 Q. Does COM in this sentence refer to

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1 you?

2 **A. That is me, COM, yes.**

3 Q. And what is the first chemical  
4 development plan? Let me rephrase that. What in  
5 general is a chemical development plan in Shorts?

6 MR TRAINOR: Objection. At this time?

7 MS CASSIDY: At this time?

8 **A. Members of the team wanted to get**  
9 **some information how we intend to proceed.**

10 MS CASSIDY: I am going to hand you a  
11 document which was previously marked as Sparf  
12 Exhibit 12 which we will mark as Meese Exhibit 13.

13 (Exhibit 13 marked for identification)

14 MR TRAINOR: Do you need him to make  
15 reference to any of these Exhibits?

16 MS CASSIDY: For now the timetable, the  
17 rest can get set aside.

18 MR TRAINOR: I am trying to help him  
19 out.

20 MS CASSIDY: Dr Meese, we have handed  
21 you what was previously marked as Sparf Exhibit 12  
22 and has been marked in this case as Meese Exhibit  
23 13, a document bearing Bates numbers PT 02075781  
24 through PT 02075809. If you could please look  
25 through this Exhibit and then let me know if you

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1 recognize this document?

2 A. I am losing track with so much paper  
3 on the table.

4 MR TRAINOR: She has asked you to look  
5 through it and see if you recognize it.

6 A. These are slides with intentions or  
7 proposed ways to proceed saying like we could do  
8 something.

9 MS CASSIDY: So for now looking just at  
10 the very first page labeled PT 02075781?

11 A. Okay.

12 Q. This is a document labeled: The  
13 first team meeting, correct?

14 A. I don't know here. We have got it  
15 here, yes, 19th September obviously. That is what  
16 it says here too.

17 Q. And did you attend this meeting,  
18 Dr Meese?

19 A. Yes, I was mentioned here so I think  
20 I attended it.

21 Q. And were team meeting minutes  
22 prepared in the regular course of business at  
23 Schwarz?

24 MR TRAINOR: Objection. If you  
25 understand it.

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1           A. This wasn't really a team yet at the  
2 time. It's really what we would have called a  
3 pre-team. A pre-team doesn't become a team until  
4 you actually have a project that is approved by  
5 the Executive Board with the appropriate funding  
6 and everything, so this is what we would have  
7 called a pre-team meeting.

8           MS CASSIDY: And in 1997 was it the  
9 regular practice to take meeting minutes of  
10 pre-team meetings?

11           MR TRAINOR: Objection.

12           A. Well, usual. Schwarz had no  
13 experience with such early phase development and  
14 there was no usual. Sometimes yes and sometimes  
15 no.

16           MS CASSIDY: Dr Meese, do you recall  
17 what your role was in this first meeting on  
18 September 19th, 1997?

19           A. Well, generally it was my  
20 responsibility to inform the team on the progress  
21 that had been made in chemistry.

22           Q. Do you see where it says AD 3?

23           A. Yes.

24           Q. It states that synthesis in-house  
25 started September 15th. Do you recall what

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1 synthesis was started on September 15th?

2 **A. Priority of product confirmed**  
3 **(talking to himself).**

4 **That's something we would have to check**  
5 **up on in the laboratory journals. I don't recall.**

6 Q. Okay. The next sentence states:

7 "Two starting chemicals outsourced  
8 available September 24th."

9 Do you recall which two chemicals,  
10 starting chemicals were outsourced?

11 **A. No, I really can't remember which**  
12 **two that might have been.**

13 Q. Okay. If you can turn to the next  
14 page, it is the one bearing Bates number PT  
15 02075783, it is two pages?

16 MR TRAINOR: 63?

17 MS CASSIDY: 783. Do you see the second  
18 paragraph beginning:

19 "Structure similar to a compound already  
20 in approval process."

21 MR TRAINOR: The question is did you see  
22 it?

23 **A. I don't know who would have made**  
24 **that statement here.**

25 MS CASSIDY: Okay. Actually but you see

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1 where the statement is?

2 **A. Yes, of course.**

3 MS CASSIDY: And underneath it it  
4 states: "Defined chemical strategy."

5 Do you know what defined chemical  
6 strategy it might refer to?

7 **A. No, no.**

8 MS CASSIDY: And in the third bullet  
9 point it states that there is a low development  
10 risk. Do you know how the development risk was  
11 determined for this product?

12 MR TRAINOR: Objection.

13 **A. No, no I really don't know who wrote  
14 this and I can't tell you. You would have to ask  
15 the person who wrote this.**

16 MS CASSIDY: And if you could turn to  
17 page PT 02075789, it is a page titled: Chemical  
18 Development Plan. Dr Meese, did you draft this  
19 chemical development plan?

20 **A. Yes.**

21 Q. And if you look at the first line  
22 where it says:

23 "Aim synthesis of a key intermediate  
24 (semi-protected hydroxy metabolite)".

25 Do you see that?

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1           A.   Yes.

2           Q.   Is the semi-protected hydroxy  
3 metabolite the only key intermediate that you were  
4 trying to synthesize?

5           MR TRAINOR:  Objection.

6           A.   I need to look for something.

7           MR TRAINOR:  Is your question at this  
8 time or at any time?

9           MS CASSIDY:  At this time.

10          A.   I can't find it here.  There were a  
11 lot of people involved in this back then and it  
12 was always very busy and hectic and I know it was  
13 the team who asked me because they wanted to know  
14 what the current status was, and that was why  
15 I provided this report.

16          Q.   Also in that section related to --  
17 called "Aim" it goes on to say:

18               "Ready to give new prodrugs in two  
19 simple steps."

20               What was meant by -- strike that.

21               Were there already two simple steps that  
22 you had in mind for synthesizing the prodrug from  
23 the semi-protected hydroxy metabolite?

24          A.   I am still looking for the structure  
25 which pertains to 9.  At this time it was

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1 primarily paper chemistry, just to signify the  
2 team members because otherwise as present they ask  
3 each week several times, so ...

4 Q. With the understanding that at this  
5 time it was primarily paper chemistry, do you  
6 recall why you believe the two steps to the new  
7 prodrug would be characterized as simple?

8 MR TRAINOR: Objection.

9 A. Well, we are still talking about  
10 paper chemistry based on our experience up until  
11 then.

12 MS CASSIDY: When you say "based on our  
13 experience up until then", are you referring to  
14 the knowledge that you had based on publications  
15 that were available to you prior to  
16 September 19th, 1997?

17 A. Yes, both, all experience in  
18 chemistry in general.

19 MS CASSIDY: If you go to the next line  
20 where it says "Prerequisite", it then says:

21 "Cut down the number of steps from 9  
22 (Pharmacia-Upjohn) to 3 to 5 (Shorts Pharma),  
23 design of a new patent-free route."

24 MR TRAINOR: Hold on, there was no  
25 question yet.

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1           A. The answer was yes, that was the  
2 point.

3           MS CASSIDY: And why were you trying to  
4 cut down the number of the steps in the Pharmacia  
5 Upjohn process?

6           MR TRAINOR: Objection. Go ahead.

7           A. It is always general in chemistry  
8 and pharmaceutical chemistry favorable to have  
9 short processes because long processes are lengthy  
10 during the production, expansive and there is no  
11 word -- and if it's possible to cut down the  
12 number of steps during a certain route, that's  
13 progress.

14          MS CASSIDY: Was this listed as a  
15 prerequisite because the intent was to develop that  
16 shortened synthesis prior to developing new  
17 prodrugs?

18          A. Well, it was a concession to the  
19 executives who said that everything was taking too  
20 long.

21          MS CASSIDY: And if you jump down to the  
22 section in bold where it says "timelines", at the  
23 third point you proposed that the first set of  
24 prodrugs would be available November 14th?

25          A. Yes.

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1 Q. And you expected the first set of  
2 prodrugs, you would have greater than three  
3 prodrugs; is that correct?

4 A. No, that was a suggestion.

5 Q. A suggestion?

6 A. Yes. The whole material was racemic  
7 at that time. That should be noted.

8 Q. Had you been involved in the  
9 development of a new drug product before?

10 A. Yes, but on completely different  
11 indications.

12 Q. Based on your prior experience was  
13 the two month timeframe from when this chemical  
14 development plan was prepared to November 14th,  
15 when you had the expectation of a first set of  
16 prodrugs a fast period of time to prepare that  
17 first set of prodrugs for the pharmacology  
18 department?

19 MR TRAINOR: Objection.

20 A. Yes, it was ambitious.

21 MS CASSIDY: Was there a particular  
22 reason for the ambitious schedule in this project?

23 MR TRAINOR: Objection.

24 A. I could only speculate on that. All  
25 I can make statements on is chemistry. I don't

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1 know.

2 MR TRAINOR: How are you doing, okay?

3 A. Yes, I am okay. Thank you.

4 MS CASSIDY: Dr Meese, if you need a  
5 break feel free to let me know and stop whenever  
6 you need.

7 A. No, no, we can proceed. If you  
8 reach a certain stage here.

9 MS CASSIDY: If you could please turn to  
10 PT 02075791.

11 A. Yes.

12 Q. In the top right-hand corner --  
13 sorry top left-hand corner?

14 A. This one?

15 Q. Yes, that one. In the top left-hand  
16 corner the chemical structure depicted is  
17 tolterodine, correct?

18 A. Yes.

19 Q. And the middle structure depicted  
20 where it says "active metabolite", that is  
21 referring to 5-HMT; is that correct?

22 A. Yes, that is true. Still racemic  
23 shown on these schemes.

24 Q. Okay. What are the structural  
25 differences between tolterodine and 5-HMT?

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1 MR TRAINOR: Objection.

2 THE INTERPRETER: He indicated the left  
3 groups of both.

4 A. Methyl group is replaced by  
5 hydroxymethyl group.

6 MS CASSIDY: In 1997 at the start of  
7 this project based on the public information that  
8 you had discussed with Dr Sparf and the structures  
9 of tolterodine and 5-HMT, what conclusions, if  
10 any, could you draw about the differences between  
11 5-HMT and tolterodine's chemical properties?

12 MR TRAINOR: Objection.

13 A. There was no chemical  
14 characterization of these. They weren't  
15 available.

16 MS CASSIDY: And in 1997 did you have  
17 any understanding as to the clinical significance  
18 of the added benzyl hydroxy group on 5-HMT?

19 MR TRAINOR: Objection.

20 A. No.

21 MS CASSIDY: Okay. And looking at the  
22 structures of tolterodine and 5-HMT based on the  
23 knowledge that you had in 1997 as you were  
24 beginning work on this project, what did you  
25 anticipate would be the easiest way to derivatize

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1 5-HMT?

2 MR TRAINOR: Objection.

3 A. We had no information concerning the  
4 chemical reaction or properties of any of these  
5 then. No information at all.

6 MS CASSIDY: In 1997 had you begun to  
7 develop a method of derivatizing 5-HMT yet?

8 A. I would have to look it up in the  
9 lab journals. I just don't know off the top of my  
10 head. Not that exactly, no.

11 Q. Can you turn to PT 02075797?

12 A. Yes, the first one.

13 Q. Could you take a minute to review  
14 the pages starting on 797 through the end of the  
15 document at PT 02075809?

16 A. Okay. I would like to suggest that  
17 we don't spend too much time going into this.  
18 These were just mind games, concepts that I was  
19 playing around with together with the chemists in  
20 the team that I was discussing these options with,  
21 but there was no experimental indication for any  
22 of these.

23 Q. So for each of these seven concepts  
24 these were the paper chemistry that we were  
25 talking about earlier?

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1           A.   Yes.

2           Q.   Do you recall whether there was an  
3 attempt to reduce any of these seven concepts to  
4 actual chemistry at any point?

5           A.   Yes, but at that time we were under  
6 extreme time constraints, we didn't have much time  
7 for a slow systematic development so we decided to  
8 develop this paper chemistry and to look at the  
9 potential key steps and to proceed if one of the  
10 potential key steps is available and it works, we  
11 would focus on that. And as soon as one of the  
12 concepts fail you different reasons, and this was  
13 actually the case, both of them failed. Then we  
14 will skip it and proceed with the most promising  
15 route.

16           MS CASSIDY: We have been going a little  
17 bit over an hour and I am about to switch  
18 documents, do you want to take a break now?

19           MR TRAINOR: Yes. Should we break for  
20 lunch?

21           MS LO: Yes, it should be set up  
22 outside.

23           THE VIDEOGRAPHER: Off the record at  
24 12.43. This is the end of Tape Two in the  
25 deposition of Dr Claus Meese.

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1 (The Lunch Recess)

2 THE VIDEOGRAPHER: This is the beginning  
3 of Tape Three, Volume One and a continuation in  
4 the deposition of Dr Claus Meese. On-the record  
5 at 1.33.

6 MS CASSIDY: Dr Meese, I am going to  
7 hand you what has been marked as Exhibit 14  
8 bearing Bates numbers PT 02075813.

9 (Exhibit 14 marked for identification).

10 Do you recognize this document,  
11 Dr Meese?

12 **A. Probably yes.**

13 Q. Did you draft this document,  
14 Dr Meese?

15 **A. Yes.**

16 Q. And this was an update to the  
17 chemical development plan from October 3rd, 1997,  
18 correct?

19 **A. Yes.**

20 Q. In the update section you noted that  
21 the vacations of collaborators in training of an  
22 apprentice were postponed and work of academics  
23 was extended on weekends and holidays, was this  
24 due to the extreme priority of the project that we  
25 discussed earlier?

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1           A. Yes, the boss made extreme pressure  
2 and the time constraint was irrational.

3           Q. Were you aware of any concerns that  
4 another company was also attempting to develop a  
5 prodrug from 5-HMT at the same time?

6           A. Yes, everybody feared that there  
7 were some signs for a Japanese company and another  
8 one, but I haven't the data on that, so it was a  
9 very competing fear of research, this sector on  
10 incontinence. That's true. In the field of  
11 incontinence research.

12          Q. Was there any concern that Pharmacia  
13 Upjohn was also pursuing a 5-HMT prodrug?

14          A. Yes, both companies were mentioned  
15 in this context.

16          Q. And the Pharmacia Upjohn, Pharmacia  
17 Upjohn had already patented a method of  
18 synthesizing 5-HMT; is that correct?

19          A. Yes, yes.

20          Q. And that was the method that you  
21 were modifying in order to develop your own  
22 synthesis of 5-HMT?

23          A. That's right, yes.

24          Q. Once you have 5-HMT, starting from  
25 5-HMT did you expect the synthesis of a prodrug

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1 from 5-HMT to be difficult?

2           A. We haven't had excellent experience  
3 and practice, but my experience from organic  
4 chemistry in different projects it was that there  
5 will be a way to get a stable derivative which can  
6 serve as an intermediate, and once we have an  
7 intermediate which is relatively stable the  
8 intermediates can mostly modify it in one to two  
9 steps to give a new compound. This is possible.  
10 Maybe it might not be the ideal new compound but  
11 it is new anyway.

12           Q. In the intermediate that you were  
13 referring to would that be the 5-HMT intermediate?

14           A. Yes.

15           Q. I am going to hand you a document  
16 which will be marked as Exhibit 15 and it bears  
17 Bates numbers PT 02075817 through PT 02075849.

18           (Exhibit 15 marked for identification)

19           If you can take a look at the first page  
20 of the document. This document is titled: The  
21 second team meeting NCE incontinence. Dr Meese,  
22 for now we are just going to talk about the  
23 minutes, if you want to a look at the first page  
24 and we will talk about the synthesis in a little  
25 bit.

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1           A. I think so, yes. It cannot contain  
2 much information. When the project was started on  
3 September 28th this is one month later, what  
4 should happen during that time, its ...

5           Q. If I can direct your attention to  
6 the section labeled AD 2 on the very first page?

7           A. Yeah.

8           Q. The second paragraph states:

9           "First choice prodrugs will be the  
10 acetyl or benzyl derivatives."

11           Do you recall why these were the first  
12 choice prodrug derivatives?

13           A. This was simply because benzyl  
14 compound was starter material, an ester was one  
15 step so it was -- we haven't got the time to be  
16 ingenious, we took what was on the shelf.

17           Q. Because an ester was one step.

18           A. I wouldn't hesitate to call it an  
19 ester. If you mind go ahead and call it acetate  
20 but I wouldn't have a problem calling it an ester,  
21 no.

22           Q. To clarify, these are first choice  
23 prodrugs because the ester would have been a one  
24 step derivatization?

25           MR TRAINOR: Objection.

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1           A. Yes, for chemical reasons it was  
2 simple.

3           MS CASSIDY: And if you turn to page PT  
4 02075819, this is the update two to the chemical  
5 development plan. Did you draft this update to  
6 the chemical development plan?

7           A. Yes, and normally there was a copy  
8 was forwarded to this pre-team that came together.

9           Q. And if you go down to where it says  
10 "first goal"?

11          A. Yes.

12          Q. "The first goal includes making the  
13 hydroxy metabolite available for BA (chemically  
14 and enzymatically)"?

15          A. Yes.

16          Q. What was the difference between the  
17 chemical and enzymetic process of obtaining the  
18 hydroxy metabolite?

19          A. The chemical synthesis was not  
20 developed at this very early time and the  
21 enzymetic was expected to be more rapid. It is a  
22 simple incubation that's suitable with microsomes  
23 preparations or enzyme, incubation with  
24 microsomes, mostly S9 supernatant microsomes were  
25 used or liver, whole liver microsomes. They have

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1 a high activity to metabolize suitable drugs, so  
2 in a subsequent step it is possible to isolate the  
3 metabolism products. However, only a very, very  
4 low amount, but mostly it is suitable for the  
5 bio-analytics, they don't need much. They just  
6 need a few microgram or nanogram, even as a  
7 reference for the development of the analytics  
8 which was not made at this time point. Chemistry  
9 is more efficient but it is more time consuming.

10 Q. If you turn to the page PT 02075821  
11 and this goes through PT 02075849?

12 A. Yes.

13 Q. The concept, the chemical synthesis  
14 concepts that are disclosed in these pages, at  
15 this stage were these still paper chemistry  
16 concepts?

17 A. Yes, and several weeks later we  
18 noted that this doesn't work. This is just a  
19 brief comment to give you the information. We got  
20 a black tar which it's funny it landed in the  
21 west, so that's chemistry. It can happen.

22 Q. When you say this doesn't work you  
23 were referring to the Shorts Pharma concept one?

24 A. This one, yes. Yes, I have a  
25 feeling what the reason might be but it is just a

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1 speculation. I never would repeat that reaction.  
2 I will never forget the flask of black syrup that  
3 was there in the chromatographic serums gave us  
4 hundreds of side products so it was not a very --  
5 but that's typical for paper chemistry. It can be  
6 splendid but it can be a disaster.

7 Q. At the time of the second team  
8 meeting, October 24th 1997, you had not performed  
9 any of these concepts yet?

10 A. Well, I don't have these details in  
11 hands, but maybe there was a hard when we  
12 switched, chemistry which has been published by  
13 the Upjohn patents because I have the feeling this  
14 really might actually work, it is not ideal but it  
15 might work. It is better than erection. It looks  
16 theoretically splendid but it doesn't work.

17 Q. When you were testing the concepts  
18 throughout the development of festoterodine did  
19 you run the syntheses yourself or did you have  
20 someone else perform the actual chemical testing?

21 A. Both. It depends on the capacity  
22 that we have in our labs. If possible we do it in  
23 our labs, but in several cases people were all  
24 busy and so we have had so-called Contract  
25 Research Organisations, external CROs which got

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1 some data and information that we have and we  
2 agreed that they work for a given time until they  
3 have a result, positive or not. It was to  
4 compensate the poor, let me say, amount of  
5 co-workers that we had. We didn't have enough  
6 people to quickly work on that, so...

7 Q. Were there any other -- sorry, were  
8 you finished?

9 A. As far as I see now the other  
10 proposals didn't work at all so we shouldn't look  
11 too much into details of projects or ideas that  
12 died very early.

13 Q. I am going to hand you a document  
14 that will be marked as Meese Exhibit 16. It's  
15 been previously marked as Sparf Exhibit 13 and  
16 bears the Bates number PT 02075853 through PT  
17 02075865.

18 (Exhibit 16 marked for identification).

19 Dr Meese, do you recognize this  
20 document?

21 A. Yes, I do recognize it. It's from  
22 me. It's the same story, these are ideas which  
23 have not been publicly realized or investigated,  
24 elucidated. It is bio-analytics, yes, I know  
25 that.

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1 MR TRAINOR: Let's wait for a question.

2 Let's wait for her to ask a question, okay?

3 A. Okay.

4 MS CASSIDY: If you could turn to the  
5 first page that's titled "Third team meeting".

6 And did you attend this meeting, Dr Meese?

7 A. Obviously I find my name there, yes.

8 Q. And if you look at AD 2 in bold  
9 there is a sentence:

10 "Post meeting note H. Boekens C. Meese,  
11 P. Ney and B. Sparf decided that the acetyl  
12 isobutyryl and ethylcarbonate prodrugs of the  
13 metabolite should be synthesized first."?

14 A. That describes some progress.

15 Q. Do you recall why you selected these  
16 three for the synthesis of the first prodrugs?

17 A. Where does it say that -- oh, down  
18 there. I think simply because some initial  
19 experiment showed the compounds can be made. It  
20 was a very practical reason at that time. We knew  
21 we can do work with these compounds and so we  
22 decided to take them for the animal studies in  
23 order to investigate the metabolic stability.

24 Yes, I think that's it at that time.

25 Q. When you say "we knew we can do work

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1 with these compounds", did you mean you knew you  
2 could synthesize those compounds?

3 **A. Yes.**

4 **Q.** And you knew that based on your  
5 knowledge of chemistry?

6 **A. Yes.**

7 **MR TRAINOR:** Hold on, let her finish the  
8 question.

9 **MS CASSIDY:** Based on your knowledge of  
10 chemistry leading up to 1997?

11 **MR TRAINOR:** Objection.

12 **MS CASSIDY:** Let me rephrase that. You  
13 knew this based on your knowledge of chemistry  
14 available to the public up to 1997?

15 **A. Yes, we already made those compounds**  
16 **in small amounts and if it was possible we can, of**  
17 **course, make a resynthesis to provide even more**  
18 **for the animal studies and additional**  
19 **bio-analytical studies of in-vitro incubations.**

20 **MS CASSIDY:** So as of December 2nd, 1997  
21 you had already synthesized prodrugs of the  
22 metabolite based on the acetyl isobutyryl and  
23 ethyl carbonate derivatizations?

24 **MR TRAINOR:** Objection.

25 **A. Yes, that's right.**

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1 MS CASSIDY: Do you recall when you  
2 first synthesized each of those prodrugs?

3 A. I imagine material was racemic.  
4 Material was, the chiral material was obtained  
5 later, optical, pure. We are learning a lot.

6 MS CASSIDY: If you look in AD 2 it  
7 states: "Enantiomer separation will be done on  
8 the final product."

9 Were you anticipating that separating  
10 the enantiomers would be a difficult process?

11 A. Yes, sure, because we have tried it  
12 before and we failed, so we were frightened that a  
13 failure might occur again.

14 MS CASSIDY: If you look at the line  
15 labeled AD 6 it states that: "The first draft of  
16 the mock patent distributed and discussed." What  
17 is a mock patent?

18 MR TRAINOR: Objection.

19 A. At that time I didn't know what it  
20 is. And I was told it is a draft of a patent just  
21 to write it -- kind of like writing a fictional  
22 type patent that can then be amended by others as  
23 soon as facts are found.

24 MS CASSIDY: I am going to hand you a  
25 document marked as Meese Exhibit 17 bearing Bates

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1 numbers PT 02075871 through PT 02075889.

2 (Exhibit 17 marked for identification)

3 Do you recognize this document,

4 Dr Meese?

5 **A. Yes, yes.**

6 Q. Did you draft any portions of this  
7 document?

8 **A. Yes, yes, all of it and some of it**  
9 **was already distributed at earlier pre-project**  
10 **team meetings. This basically served to help**  
11 **people remember what developments had taken place**  
12 **since the beginning.**

13 Q. If you could please turn to PT  
14 02075875?

15 MR TRAINOR: Just wait for the question.  
16 We are just getting you there.

17 MS CASSIDY: The synthesis that's  
18 depicted on this page, is this the Pharmacia  
19 Upjohn method that you were modifying?

20 **A. Yes. Essentially yes.**

21 MS CASSIDY: At this time in the  
22 synthesis depicted on this page does it already  
23 include the Shorts Pharma modifications to the  
24 original Pharmacia Upjohn route?

25 **A. Yes.**

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1 MR TRAINOR: Objection.

2 A. Again, paper chemistry ideas.

3 MS CASSIDY: So as of January 2nd, 1998  
4 you had not begun actual synthesis of this Shorts  
5 Pharma modification of the Pharmacia Upjohn route?

6 MR TRAINOR: Objection.

7 A. I don't remember exactly, but I have  
8 the feeling -- none of the schemes represent a  
9 route which is very close to the final process.  
10 These are all experimental, descriptions and  
11 observations as far as I see now. It is still  
12 paper chemistry, and in practice most of them  
13 failed. It is frustrating but it is normal in  
14 science. It is normal.

15 MS CASSIDY: Could you please turn to PT  
16 02075881?

17 A. You are faster.

18 MR TRAINOR: I am faster? Not always.

19 A. Thank you.

20 MS CASSIDY: If you look under the  
21 conclusion it states:

22 "In the given system the phenolic  
23 hydroxy group shows a higher reactivity than the  
24 benzylic hydroxy group."?

25 A. Yes.

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1 MS CASSIDY: Was this a surprise that  
2 the phenolic hydroxy group was more reactive than  
3 the benzylic hydroxy group?

4 MR TRAINOR: Objection.

5 A. That was.

6 MS CASSIDY: And why was that  
7 surprising?

8 MR TRAINOR: Objection. To him?

9 MS CASSIDY: To you?

10 A. Yes, yes. The whole system for  
11 hydroxy benzyl alcohol, as I mentioned initially,  
12 is a very strange, very strange from a point of  
13 chemistry, and the benzyl alcohol can react in  
14 very strange ways. It depends on the activating  
15 function of the phenolic hydroxy group, that is  
16 what I initially mentioned as push pull effect.  
17 So everything is surprising. It depends on the  
18 whole structure of the molecule. Nobody can  
19 predict anything here, but we learn from this. It  
20 was very useful to make these experiments.

21 In this here, the scheme, a potential  
22 solution to the problems with this remarkable in  
23 respect to the enzymetic approach which  
24 demonstrated that we can solve the problems which  
25 are addressed and observed before by this

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1 approach, but it actually works.

2 MR TRAINOR: The record should just  
3 reflect that the witness is looking at the page  
4 ending in 83 for that last bit of testimony.

5 A. 83, yes. This is a remarkable  
6 result because we met the required compounds and  
7 this leads to the result of that, what we hoped  
8 benzylic modification might be helpful clearly  
9 proved that it didn't work. So that's part of the  
10 whole invention, even if we have on this way many  
11 failures.

12 MS CASSIDY: Dr Meese, earlier you  
13 mentioned a push pull effect with regard to the  
14 two hydroxy groups, can you explain what you mean  
15 by the push pull effect?

16 MR TRAINOR: Are you asking him  
17 generally or referring to something in this  
18 document, just so we can have it?

19 MS CASSIDY: Generally he mentioned it.  
20 I don't believe it was mentioned in the document.

21 MR TRAINOR: Sorry.

22 A. I don't have the scheme here. If we  
23 look at the four hydroxy benzyl structure, and the  
24 benzyl alcohol has 1 OH group, and this OH group  
25 is modified, for example, by an acyl group to give

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1 an ester. And the phenolic hydroxy group, the  
2 para sub situation loses one proton, then we have  
3 phenolate in the para subset, para position to the  
4 benzyl position. And the negative charge of the  
5 phenolate presses electron density in the benzyl  
6 group if there is a good leaving group which is  
7 capable of absorbing electron density so we will  
8 have a cleavage of this group.

9 In other cases we have even observed  
10 that normal benzyl derivatives can be alkylating  
11 agents. It is a species where a positive charge  
12 is at a common better. And this species is  
13 reactive and in many cases forms carbon, carbon  
14 ponds, what is not so easy in our case. So it  
15 became clearer and clearer with these experiments.  
16 Yes, I think we have that. So it was a  
17 frustrating presentation of many experiments that  
18 did not work.

19 With the expectation of the first  
20 synthesis of benzyl esters in this system, which  
21 was mentioned before are not stable, and the  
22 physiological conditions rapidly cleaved, and we  
23 have from the Bio-analytical Department extensive  
24 data on the cleavage rate and that's also NPH  
25 dependence, but this is all not useful for the

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1 development of pharmaceuticals with only findings  
2 that demonstrate the limitations of certain  
3 routes. Okay. That is what we can say to this  
4 paper.

5 MS CASSIDY: Are you saying that you  
6 observed that the phenolic OH group was more  
7 reactive than the benzylic OH group?

8 MR TRAINOR: Objection. Can you  
9 translate that, please?

10 A. Yes, in respect to the ester  
11 formation under the usual esterification  
12 conditions.

13 MS CASSIDY: Can you turn to 02075855,  
14 and under the comment it is stated:

15 "It is obvious to try to take full  
16 advantage of the higher reactivity of the phenolic  
17 hydroxy group of the hydroxy metabolite."?

18 MR TRAINOR: Could you translate that,  
19 please?

20 MS CASSIDY: And when you say it is  
21 obvious to take full advantage of the higher  
22 reactivity was that based off of your knowledge,  
23 your chemical knowledge prior to 1997?

24 MR TRAINOR: Objection.

25 A. It is hard to say. I cannot

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1 actually really not remember. These observations  
2 came up time and again and all the details of our  
3 work, and they were observed many times throughout  
4 the course of process. I can't put a date to it  
5 really.

6 MS CASSIDY: Can you please turn to PT  
7 02075889?

8 A. Thank you.

9 MS CASSIDY: Under the conclusion it  
10 states:

11 "The reaction conditions are well  
12 documented in the chemical literature."

13 Were the reaction conditions for  
14 converting to prodrugs -- strike that. Were the  
15 reaction conditions for all of the derivation to  
16 prodrugs that you were attempting well documented  
17 in the chemical literature?

18 MR TRAINOR: Objection.

19 A. Yes. This page rules out extensive  
20 literature research worldwide, and I found a  
21 number of papers which dealt with the strange  
22 behavior of the structure for hydroxy benzyl  
23 alcohol, and from one of the papers, I remember it  
24 was a Japanese paper, showed that silylation  
25 S-I-L-Y-L might be Regio selective and the

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1 cleavage of the silyl groups might be also chemo  
2 selective. It depends on the nature of the silyl  
3 group and the reagents used for the cleavage.

4 And again it could be differentiated in  
5 the system for hydroxy benzyl alcohol is the newly  
6 introduced silyl group on the phenolic side or the  
7 benzylic side. It looked brilliant but as we had  
8 a closer look we recognized that this has only  
9 academic interest, and I doubted that we will  
10 never can develop an industrial process on the  
11 basis of the different selectivities. So it is  
12 typical for this kind of chemistry, you find  
13 fascinating alternatives and then we investigate  
14 it, the practice, the reality that we had to  
15 recognize that this was not --

16 THE INTERPRETER: It wasn't the greatest  
17 idea of all times.

18 A. Fine, fine.

19 MS CASSIDY: I am going to hand you what  
20 will be marked as Exhibit 18, a document bearing  
21 Bates numbers PT 02075893 through PT 02075903.

22 (Exhibit 18 marked for identification)

23 Dr Meese, do you recognize this  
24 document?

25 A. Yes. Yes.

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1 MS CASSIDY: And did you draft this  
2 document?

3 A. Yes. It is a very early report as  
4 you see. At the beginning of 1998 this was the  
5 attempt to inform the pre-project team of the  
6 status. Pre-project team.

7 MR TRAINOR: Just wait for the question.

8 MS CASSIDY: And at this time 17  
9 prodrugs had been prepared; is that correct?

10 A. We have a table here. Yes. As far  
11 as I remember all compounds which have been  
12 prepared were racemic in structure. Yes.

13 Q. And if you look at page PT 02075895?

14 A. Exactly, that is the table which  
15 gives the status, yes of August '98, yes. Yes.

16 Q. And if you look at SPM number 7475,  
17 it's about six rows down?

18 A. Yes.

19 Q. It has a structure of HO-/-IBUT  
20 correct?

21 A. Exactly. This is racemic  
22 festoterodine based. 7475, yes, that's right.  
23 Yes. Yes.

24 Q. I am going to hand you a document  
25 which will be marked as Exhibit 19 which bears

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1 Bates numbers PT 02075909.

2 (Exhibit 19 marked for identification)

3 **A. Thank you.**

4 MR TRAINOR: Since she's looking for  
5 something can we take a short break?

6 MS CASSIDY: Yes.

7 THE VIDEOGRAPHER: Going off-the-record  
8 at 2.36.

9 (Short Recess)

10 THE VIDEOGRAPHER: Back on the record at  
11 2.57.

12 MS CASSIDY: Dr Meese, I am also going  
13 to hand you a document that is a translation of  
14 Exhibit 19. You should note for the record that  
15 this translation states that it is a translation  
16 of Bates number PT 02050579, however that is a  
17 typo and it should state that it is a translation  
18 of PT 02075909.

19 (Exhibit 20 marked for identification)

20 MR TRAINOR: For the record Exhibit 20  
21 is the translation of Exhibit 19.

22 MS CASSIDY: Yes, that is correct.

23 **A. Thank you.**

24 MS CASSIDY: Dr Meese, if you would like  
25 to direct your attention to Exhibit 19, that is

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1 the German version of Exhibit 20. Do you  
2 recognize this document?

3 **A. Yes, I do.**

4 Q. Is this your handwriting?

5 **A. Yes, it is.**

6 Q. And if you look there is a line  
7 through the middle of the page, if you look below  
8 that line on the left-hand side there is a table  
9 of five compounds, do you see that?

10 **A. Yes.**

11 Q. And if you look at compound  
12 Number 5?

13 **A. Yes.**

14 Q. This is the HO/IBUT formulation?

15 **A. Exactly.**

16 Q. Is this formulation the racemic of  
17 the festoterodine drug?

18 **A. Yes, if it comes from February 1998  
19 it must be racemic.**

20 Q. Okay. There is an arrow next to it?

21 **A. Yes.**

22 Q. And underneath that a statement that  
23 it says:

24 "Excellent +++ to moderate ++ liberation  
25 of HYDR.MET form prodrug."

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1           Is this referencing the fact that there  
2 was -- that this metabolizes into the 5-HMT?

3           MR TRAINOR: Objection.

4           A. Exactly. The liberation or the  
5 formation of the free HMT metabolite, yes, that's  
6 right, metabolite. It is very early data, yes, on  
7 a qualitative basis.

8           MS CASSIDY: Dr Meese, I am going to  
9 hand you a document which will be marked as Meese  
10 Exhibit 21 bearing Bates numbers PT 02075907.

11           (Exhibit 21 marked for identification)

12           Do you recognize this document?

13           A. Yes.

14           Q. Did you draft this document?

15           A. Yes.

16           Q. Under update five it states that an  
17 in-vitro assay with human liver homogenate was  
18 conducted?

19           A. Yes, that's right.

20           Q. Were you involved in the connection  
21 of this assay?

22           MR TRAINOR: Objection.

23           A. That was with the exception of the  
24 preparation of the starting materials, the  
25 prodrugs I was not involved. It was of the

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1 Bio-analytical Department, Hilmar Boekens. That's  
2 his name there. He got a copy, of course.

3 MR TRAINOR: I think that is  
4 B-O-E-K-E-N-S.

5 MS CASSIDY: Underneath that it also  
6 states: "Efficient liberation of hydroxy  
7 metabolite."

8 **A. Yes.**

9 MS CASSIDY: And lists three compounds  
10 including HO/OI-BUT?

11 **A. Yes.**

12 MS CASSIDY: HO/OI-BUT that is referring  
13 to the racemate of the festoterodine; is that  
14 correct?

15 **A. Yes, that is correct.**

16 MS CASSIDY: And what did knowing that  
17 there was efficient liberation of the hydroxy  
18 metabolite from these compound tell you?

19 MR TRAINOR: Objection. Can you  
20 translate that question, please?

21 **A. As I mentioned before these are**  
22 **qualitative data. Later on we got more precise**  
23 **qualitative data, but efficient means that**  
24 **significant amounts of the hydroxy metabolite were**  
25 **observed in the HPLC chromatograms after**

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1 incubation of the racemic prodrugs which are shown  
2 here. So the concept, this was very important for  
3 the Board. We showed them, we offered a compound  
4 which is a potential prodrug and we showed that it  
5 is a prodrug and it is cleaved, because again in  
6 this field we have had just this one sentence, a  
7 strange bias. In German this is a dogma. That by  
8 bulky phenolic ester are not, or are very  
9 difficult cleaved by human esterases or lipases.  
10 This was almost a fatal bias because the CEO said  
11 if the prodrugs are not cleaved the whole project  
12 will die, or will be killed by him personally.

13 So we could demonstrate that even bulky,  
14 that means very, very big constitutes, B-U-L-K-Y  
15 constitutes they hinder the esterases and lipase  
16 to cleave phenolic esters. That is true but it is  
17 not a disaster as should further investigations  
18 and precise qualitative data will follow.

19 Q. Do you recognize the handwriting  
20 that's on this document?

21 A. Yes.

22 Q. Is that your handwriting?

23 A. That's mine, yes.

24 Q. I am going to hand you what's been  
25 marked as Exhibit 22, which is a translation of

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1 the handwriting in Exhibit 21.

2 (Exhibit 22 marked for identification)

3 MR TRAINOR: You keep this because you  
4 read the German.

5 A. Okay. If you want me to compare  
6 this.

7 MR TRAINOR: Let's wait for a question.

8 MS CASSIDY: In the handwriting that's a  
9 little right underneath "next challenge" which  
10 starts "patent concept".

11 MR TRAINOR: For the record this is the  
12 handwriting that is more to the right of the page.  
13 Here. This is your writing, this is German. Just  
14 don't worry about that.

15 MS CASSIDY: And underneath "patent  
16 concept" there is a dash and it says:

17 "HYDR.METAV is better."

18 A. That is an attempt to quantitate the  
19 qualitative data which was shown on the meetings  
20 by Dr Boekens. That means the word good cleavage  
21 is around 10%. That means 10% of the prodrug are  
22 observed in the HPC chromatograms, at least our  
23 very early and preliminary data.

24 MS CASSIDY: And if you recall when we  
25 were talking about your August 28th, 1997 meeting,

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1 we discussed the bioavailability of the hydroxy  
2 metabolite as being 10%, and if we need to refer  
3 back to that Exhibit we can?

4 A. Yes, I remember that.

5 MS CASSIDY: Was that why -- in view of  
6 that was the bioavailability aim from the prodrug  
7 aimed to be higher than 10% in order to improve  
8 over the hydroxy metabolite that was already  
9 known?

10 MR TRAINOR: Objection.

11 A. I think this is different. This  
12 means the formation of the hydroxy metabolite  
13 after the administration of the racemic prodrugs,  
14 that is what this data means, and the 10% which  
15 appeared there is a completely different 10%, and  
16 I mean administration of the hydroxy metabolite  
17 that is the 5-hydroxymethyl tolterodine to any  
18 animal, and I don't have any more data, so these  
19 are information that came up on some of the  
20 congresses during posters and discussions, and  
21 these data are completely different 10%.

22 That means administration of the  
23 metabolite shows only small amounts of a  
24 metabolite in any animal. I don't even know what  
25 kind of animal. I don't want to speculate here.

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1 But these are data under good analytical practice  
2 generated by the Bio-analytical Department,  
3 qualitative data, but it is a good basis to proceed.

4 Q. Okay. So the BA insufficient 10%,  
5 the 10% was data that was generated off of the  
6 prodrugs themselves?

7 A. Exactly.

8 Q. I am going to hand you a document  
9 which will be marked as Meese Exhibit 23, bearing  
10 Bates numbers PT 02075945 through PT 02075947.

11 (Exhibit 23 marked for identification)

12 A. Thanks.

13 Q. Dr Meese, do you recognize this  
14 document?

15 A. Yes, I know that. Yes, it comes  
16 from Peter Ney.

17 Q. And this document is the June 25th,  
18 1998 team meeting minutes, correct?

19 A. Yes.

20 Q. Did you attend this meeting?

21 A. Yes.

22 Q. If you look at the line AD 1 you  
23 state that:

24 "It is obvious that the availability of  
25 pure enantiomers of the prodrugs is critical."?

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1 MR TRAINOR: Can you just give me the  
2 line number?

3 MS CASSIDY: The second line under AD 1.

4 A. Yes, I see. Yes.

5 Q. How did you determine that the  
6 availability of the pure enantiomers of the  
7 prodrugs would be critical?

8 A. Simply in drug development most  
9 regulatory institutions such as the FDA or EMEA  
10 expect that the individual enantiomers of a drug  
11 which is under development have to be elucidated  
12 and given and presented. It is a state of the art  
13 that the enantiomers have to be available for all  
14 in-vitro and later for the in-vivo studies, so we  
15 have to have those enantiomers in substantial  
16 amounts, especially if we go in human studies  
17 later.

18 Q. If you turn to the next page, PT  
19 02075947. Do you recognize this document?

20 A. Yes.

21 Q. Did you draft this update to the  
22 chemical development plan?

23 A. Yes, yes, I wrote that.

24 Q. And if you look at the third major  
25 point where it says "synthesis"?

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1           **A. Yes.**

2           Q. And you have two option, the P&U  
3 route and underneath that it says "alternatives"?

4           **A. Yes.**

5           Q. Does this indicate that as of  
6 June 25th, 1998 when this chemical development  
7 plan was updated you were still developing the  
8 chemical synthesis route to 5-HMT?

9           **A. Yes, in parallel.**

10          Q. Since you were developing in  
11 parallel were you purchasing 5-HMT1 to use as a  
12 starting point for the prodrugs synthesis?

13          MR TRAINOR: Objection.

14          **A. I have to think it over, it's a long**  
15 **time ago. I remember we developed some activities**  
16 **to involve our own company in France, a company**  
17 **Siloc SR, to embark on a programme to support us**  
18 **as with raw materials. Then we contacted Dynamite**  
19 **Nobel, which was located very close to Schwarz**  
20 **Pharma, so we had an easy communication.**

21          MS CASSIDY: Dr Meese, I just want to  
22 clarify for the record, first when you said yes,  
23 you were working in parallel, when you said in  
24 parallel were you referring to the two synthesis  
25 routes, or to the synthesis route and the prodrug

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1 development?

2 MR TRAINOR: Objection. There is more  
3 than two routes referenced in this paper.

4 A. The metabolite or intermediate that  
5 was our primary goal. That is what we wanted to  
6 have, the hydroxymethyl. We got the complete  
7 documentation and started the work.

8 MS CASSIDY: And when you were working  
9 on the synthesis route you were working on the P&U  
10 route and the Heck-Cuprate route, H-E-C-K  
11 C-U-P-R-A-T-E?

12 A. Yes.

13 Q. And Reformatski,  
14 R-E-F-O-R-M-A-T-S-K-I, in parallel?

15 A. Yes, the most advanced route for the  
16 production on a larger scale was with the P&U  
17 route, Pharmacia Upjohn. Yes. And the other  
18 variance Heck-Cuprate route was on a laboratory  
19 scale at the Max Planck Institute in Mullheim.  
20 And we have had the chemistry under control, but  
21 what we were -- where we were without any success  
22 was the separation of the enantiomers  
23 corresponding to Pharmacia Upjohn patents. They  
24 didn't work. In order to get -- do I have  
25 questions to this point?

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1           In order to get the enantiomers even in  
2           small amounts we contacted, for example, the  
3           University of the Munster. They have a chiral --  
4           they have chiralstation there in phases, columns  
5           that are capable of separating the enantiomers,  
6           however on a small scale.

7           Q. Dr Meese, can you please turn back  
8           to Exhibit 19 for a minute?

9           A. Yes.

10          Q. In Exhibit 19 underneath the line on  
11          the left-hand side there are the five prodrugs  
12          that we discussed?

13          A. Yes.

14          Q. That had been tested for their  
15          metabolic activity?

16          A. Yes.

17          Q. What was the source of the starting  
18          material to synthesize the prodrugs that were used  
19          in the experiment summarized in this table?

20          MR TRAINOR: Objection.

21          A. You mean the chiralty?

22          MS CASSIDY: No, what was the source of  
23          the starting material to synthesize the prodrug?

24          A. A precise autwat would be if I have  
25          the laboratory journal and look at February 17th,

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1 but I think it is perhaps in our lab. At that  
2 time we haven't had any significant scaleout.

3 MS CASSIDY: So as of February 17th, you  
4 had not synthesized the 5-HMT metabolite using one  
5 of the syntheses that you were developing  
6 in-house; is that correct?

7 MR TRAINOR: Objection. Can you  
8 retranslate that question back, please? It is  
9 syntheses.

10 THE INTERPRETER: That is why I am  
11 having problems reading this, sorry.

12 A. We have made it but the racemic  
13 material. No, no, we have racemic material made  
14 February because we file out patent, and the first  
15 patent in May 1998 in May, and we showed a number  
16 of derivatives and a number of biological data in  
17 this year, in this first priority patent, so  
18 I have to look, of course, at the laboratory  
19 journal but I think February was the time where we  
20 have had the metabolite in the racemic form. Yes.  
21 You can see it here in this handwritten text in  
22 the middle here. What we are doing right now  
23 di-hydroxy, the metabolite and the synthesis of a  
24 substance. Di-hydroxy is a compound we are  
25 talking about, yes. It was made in-house, yes.

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1 MS CASSIDY: For the record, Dr Meese,  
2 you are looking at Exhibit?

3 A. 19.

4 Q. Thank you?

5 A. The upper part. In the lower part  
6 beyond the line there already shows some of the  
7 compounds that can only be made if you make the  
8 metabolite, and I am convinced we made it. The  
9 compound, chiral compounds were only used, I think  
10 it was in 1999.

11 Q. Dr Meese, I am going to hand you a  
12 document marked as Exhibit 24, bearing Bates  
13 numbers PT 02075955 through PT 02075967.

14 (Exhibit 24 marked for identification)

15 A. Yes.

16 Q. Do you recognize this document?

17 A. Yes.

18 Q. And this document are the team  
19 meeting minutes from August 10th, 1998, correct?

20 A. Yes, right.

21 Q. And did you attend this meeting?

22 A. Yes.

23 Q. If you would look at the third point

24 AD 3, it states that:

25 "After intense discussions it was

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1 decided to move forward the OH-/-OCOR compounds?

2 **A. Yes.**

3 **Q.** Were you involved with this  
4 decision?

5 **A. No. It was some other members of**  
6 **the team.**

7 **Q.** Do you know which members of the  
8 team were involved in that decision?

9 **A. No, I could only speculate and**  
10 **I don't want to do that. I was not involved in**  
11 **the decision.**

12 **Q.** The compounds of the general  
13 structure OH-/-OCOR that would include the  
14 festoterodine compounds; is that correct?

15 **MR TRAINOR:** Objection.

16 **A. Yes, I have not written this text**  
17 **because that is chemically not precise what you**  
18 **find under AD 3, but definitely festoterodine,**  
19 **yes. And I mean freebase.**

20 **MS CASSIDY:** And do you see the line:

21 "It is expected that further  
22 modifications of the ester-moiety may lead to  
23 bioavailability of about 50%."?

24 **MR TRAINOR:** Can you translate that,  
25 please?

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1           A. Yes, I don't know who made the  
2 statement but it was not me, but I presume by our  
3 Analytical Department or Mr Peter Ney. This is a  
4 statement, again not from me.

5           MS CASSIDY: Were you involved in  
6 discussions of what further modifications of the  
7 ester-moiety may be pursued at the time?

8           MR TRAINOR: Can you translate that?

9           A. Yes, of course. Also it was exactly  
10 the time I was on holidays with my family, so  
11 I was absent for some weeks but it is true, we  
12 were currently in discussion on this important  
13 issue, yes.

14          MS CASSIDY: And do you recall what  
15 types of modifications you were discussing at that  
16 time?

17          A. No, we have had some examples  
18 already in the first patent on the racemic  
19 skeleton. I was more interested at that time to  
20 get the enantiomers available in sufficient  
21 amounts because that was the urgent, very urgent  
22 exactly for the development.

23          Q. If you could turn the page to PT  
24 02075959?

25          A. Okay, then I was back from holidays.

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1 Q. Do you recognize this chemical plan  
2 update?

3 A. Yes.

4 Q. And did you draft this?

5 A. This, exactly this paper here?

6 Q. Yes, I will clarify. Did you draft  
7 this --

8 A. 959, yes, it is from me. Yes.

9 August 10th, yes, that's from me.

10 Q. Thank you. And if you look at the  
11 very last sentence on the page above the date and  
12 your name starting, stating:

13 "Intrinsic instability of a phenolic  
14 monoester has been detected after four months at  
15 room temperature."?

16 A. Yes.

17 Q. "(Interconversion to di-ester and  
18 hydroxy metabolite)."?

19 A. Yes.

20 Q. Which phenolic monoesters were  
21 experiencing --

22 A. I can see which one.

23 MR TRAINOR: Let's just listen to the  
24 question that she asks. Did you finish the  
25 question?

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1 MS CASSIDY: No, I will start over.

2 MR TRAINOR: Thank you.

3 MS CASSIDY: Which phenolic monoesters  
4 were found to have intrinsic instability?

5 MR TRAINOR: Objection.

6 A. I don't have any data here. This  
7 data from the Bio-analytic Department, which  
8 I wish I was informed after, as I told you I was  
9 on my holidays, I didn't know which were -- but  
10 whatever this phenolic monoesters at that time  
11 were all freebases and no salts. A very, very  
12 great difference. (Speaking in German).

13 MS CASSIDY: Why -- does it make a  
14 difference that these were freebases versus salt  
15 formations of the compounds?

16 MR TRAINOR: Objection.

17 A. Because it is expected that salt  
18 formation is capable of stabilizing a compound,  
19 and we have a compound which on the one side is an  
20 ester and on the other side is still an alcohol,  
21 and it is known that interconversions can occur,  
22 in particular if these are oils in pure compound  
23 and over such a long time. I think I wouldn't say  
24 this is a restriction to the further development.  
25 It was just an observation which some people make

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1 in the company.

2 MS CASSIDY: I am going to hand you what  
3 will be marked as Meese Exhibit 25, a document  
4 bearing Bates numbers PT 01932087 through PT  
5 01932089.

6 (Exhibit 25 marked for identification)

7 Dr Meese, have you seen this document  
8 before?

9 A. Yes, I have. Yes.

10 Q. And this is the team meeting notes  
11 from October 1st 1998; is that correct?

12 A. October 1st, yes, that's right.

13 Q. And did you attend this meeting?

14 A. Yes, I did.

15 Q. Under the section AD 1 on the first  
16 line states:

17 "Improvements in the synthesis i.e.,  
18 reduction of the steps of the P&U route have been  
19 achieved."?

20 A. Yes.

21 Q. And how long had you been working on  
22 -- strike that. You had been working on reducing  
23 the number of steps in the P&U route since the  
24 beginning of the incontinence project; is that  
25 correct?

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1                   A.   **Yes, yes.**

2                   Q.   So it took you a little over a year  
3 to finalize that synthesis?

4                   A.   **Yes, exactly. It was one of the  
5 biggest problems which came up.**

6                   Q.   And if you look down at the second  
7 full paragraph from the bottom of the page  
8 stating:

9                   "The following substances will be  
10 studied in receptor binding assays."

11 B-I-N-G-I-N-G?

12                   A.   **Yes.**

13                   Q.   Probably binding is what it meant to  
14 say. Then it lists five substances, do you see  
15 that?

16                   A.   **Yes.**

17                   Q.   How were these five substances  
18 selected?

19                   A.   I don't know, that was a decision of  
20 some of the people here Ney, Arth, Boekens. I was  
21 not involved in this section.

22                   Q.   Do you know whether Dr Sparf was  
23 involved in the selection of those five  
24 substances?

25                   A.   I see his name here, he seems to be

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1 he was a participant. I don't know.

2 Q. And we are running short on video  
3 time so if you want to take a short break right  
4 now?

5 A. Yes, okay.

6 THE VIDEOGRAPHER: Going off-the-record  
7 at 3.48. This is the end of Tape Three, Volume  
8 One of Dr Meese.

9 (Short Recess).

10 THE VIDEOGRAPHER: This is the beginning  
11 of Tape Four, Volume One and a continuation in the  
12 deposition of Dr Claus Meese. On-the record at  
13 4.07.

14 MS CASSIDY: Dr Meese, I am going to  
15 hand you what will be marked as Meese Exhibit 26,  
16 it is a copy of European application number  
17 0957073A1.

18 (Exhibit 26 marked for identification)

19 A. Thank you.

20 Q. Dr Meese, do you recognize this  
21 document?

22 A. Yes, it is.

23 Q. And I can represent to you that this  
24 is the European priority application for the 980  
25 patent that was filed on May 12th, 1998?

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1                   **A. Yes.**

2                   Q. And as of May 12th, 1998 you had not  
3 developed an enantiomeric specific synthesis of  
4 5-HMT; is that correct?

5                   MR TRAINOR: Objection.

6                   **A. That is correct.**

7                   MS CASSIDY: And as of May 12th, 1998  
8 you also had not developed an enantiomeric  
9 specific synthesis of any prodrugs of 5-HMT; is  
10 that correct?

11                  MR TRAINOR: Objection.

12                  **A. That is correct.**

13                  MS CASSIDY: And if you look at Table 1  
14 on the first page of this European application,  
15 the prodrugs that are depicted in the table, each  
16 of those were the racemic versions of the  
17 prodrugs; is that correct?

18                  **A. That is correct.**

19                  Q. And if you could look at paragraph  
20 58, which is on page 19?

21                  **A. Yes.**

22                  Q. In paragraph 58 each of the prodrugs  
23 depicted in that paragraph are examples of racemic  
24 prodrugs; is that correct?

25                  **A. Yes.**

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1 MR TRAINOR: Objection.

2 **A. Yes, it is right.**

3 MS CASSIDY: Dr Meese, could a chemist  
4 following the instructions and procedures in this  
5 European application make an enantiomerically pure  
6 version of festoterodine?

7 MR TRAINOR: Objection. Can you please  
8 translate that, and pay careful attention,  
9 Dr Meese.

10 **A. No.**

11 MR TRAINOR: I objected, but you can  
12 answer if you could know that answer.

13 **A. There is no description given of the**  
14 **chiral material given here.**

15 MS CASSIDY: Dr Meese, I am going to  
16 hand you what will be marked as Meese Exhibit 27,  
17 which is a document bearing Bates numbers PT  
18 01931871 through PT 01931883.

19 (Exhibit 27 marked for identification)

20 Dr Meese, do you recognize this document  
21 to be the January 29th, 1999 team meetings for the  
22 NCE incontinence team?

23 **A. I think so, yes.**

24 Q. And did you attend this meeting?

25 **A. Yes, I did. Yes.**

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1 Q. If you look at bullet point four,  
2 milestone decision, it states:

3 "After intense discussions it was  
4 decided to move forward with the following  
5 prodrugs."

6 And lists four prodrugs?

7 **A. Yes.**

8 Q. "Including HO/OIBUT (R)."?

9 **A. Yes.**

10 Q. And were you involved with the  
11 decision to move forward with those four prodrugs?

12 **A. No, I can't remember.**

13 Q. Do you recall who else may have been  
14 involved in this decision?

15 MR TRAINOR: Objection.

16 **A. I can only speculate.**

17 MS CASSIDY: And if you could please  
18 turn to page PT 01931875?

19 **A. Yes, yes.**

20 Q. And do you recognize this to be the  
21 eighth update to the chemical development plan  
22 dated January 29th, 1999?

23 **A. Yes.**

24 Q. And did you draft this document?

25 **A. Yes, I am.**

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1 Q. And if you could please turn to page  
2 PT 01931879, this document states that it is the  
3 present process as of January 29th, 1999 of the SP  
4 modification of the P&U route?

5 A. Yes.

6 Q. And I am going to ask you now to get  
7 Exhibit 1, the 680 patent out -- sorry, 650. And  
8 in Exhibit 1 if you could please turn to figure  
9 one?

10 A. Yes.

11 Q. And if you look at figure one can  
12 you please compare that to the process on -- in  
13 Exhibit 27, and can you please point out which, if  
14 any, of the steps in Exhibit 27 correspond to  
15 step 3 in figure one of the 650 patent?

16 MR TRAINOR: Little (iii) or?

17 MS CASSIDY: Non (iii), the bolded  
18 three, that first compound.

19 MR TRAINOR: At the top?

20 MS CASSIDY: At the top, yes.

21 A. Is that Roman, I don't understand  
22 which with three.

23 MR TRAINOR: Can you retranslate the  
24 original question with -- that includes step three  
25 just so he understands.

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1           **A. Okay, so this is Exhibit 27.**

2           MR TRAINOR: This is 27 and this is 1.

3           **A. Exactly.**

4           MR TRAINOR: And I object to the  
5 question.

6           **A. These are all the same reactions.**

7           THE INTERPRETER: So Exhibit 27.

8           **A. Compound 10 to 11 corresponds to  
9 compound 4 to compound 6.**

10          MS CASSIDY: So it is your understanding  
11 that compound 4 in the 650 patent corresponds to  
12 compound 10 in Exhibit 27?

13          **A. Could you repeat that, please?**

14          Q. So does compound 4 in the 650 patent  
15 correspond to compound 10 in Exhibit 27?

16          **A. That's right.**

17          Q. And compound 6 in the 650 patent  
18 corresponds to compound 11 in Exhibit 27?

19          **A. That's right.**

20          Q. And does compound 3 in the 650  
21 patent correspond to compound 9 on PT 01931879?

22          **A. Yes, that's right.**

23          Q. And to your knowledge is the SP  
24 modification of the P&U route the method of  
25 synthesis that was used by Schwarz for the

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1 synthesis of the 5-HMT metabolite throughout the  
2 remainder of the festoterodine project?

3 MR TRAINOR: Objection. Can I just get  
4 a clarification, so this is the last Exhibit?

5 MS CASSIDY: 27.

6 MR TRAINOR: Your question is whether  
7 the synthesis route on the page ending 879 in  
8 Exhibit 27 is the process used after January 29th,  
9 1999?

10 MS CASSIDY: Yes.

11 MR TRAINOR: Maybe you could read that?

12 A. I really would have to check that  
13 up, it's been so many years, 16 years already.

14 MS CASSIDY: I am going to hand you a  
15 document.

16 A. Well, this --

17 MR TRAINOR: Hold on, there is no  
18 question pending.

19 MS CASSIDY: You can finish what you  
20 were saying?

21 A. Well, there is an underlying  
22 difference which is significant. For example,  
23 Exhibit 27 is a different kind of resolution in  
24 contrast to the P&U process, and Exhibit 27 the  
25 resolution is done from step two to step three.

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1 MS CASSIDY: I am going to hand you what  
2 will be marked as Exhibit 28, a document bearing  
3 Bates numbers PT 01932319.

4 (Exhibit 28 marked for identification)

5 Dr Meese, do you recognize this to be  
6 the ninth update to the chemical development plan  
7 dated February 24th, 1999?

8 **A. Yes.**

9 Q. And did you draft this update?

10 **A. Yes.**

11 Q. If you look at the section labeled  
12 "prodrugs", the statement that:

13 "Chiral hydrochloride salts are  
14 available on a gram scale for toxicology,  
15 bioavailability S9 incubation stability."

16 Do you recall whether hydrochloride  
17 salts were the first salts that you used for the  
18 prodrugs?

19 MR TRAINOR: Objection.

20 **A. I must look at documents.**

21 **I actually don't know. I can only speculate but**  
22 **I don't like speculations.**

23 MS CASSIDY: I am going to hand you what  
24 will be marked as Exhibit 29, which bears Bates  
25 numbers PT 01932091 through 01932093.

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1 (Exhibit 29 marked for identification)

2 Do you recognize these to be the NCE  
3 incontinence meeting minutes from May 28th, 1999?

4 **A. Yes.**

5 Q. And did you attend this meeting?

6 **A. Yes.**

7 Q. And do you recall at this meeting  
8 presenting a route of synthesis?

9 **A. Should be this one. I think it is**  
10 **this one here, is it, PT 2093?**

11 Q. So you are looking at the synthesis  
12 on PT 01932093; is that correct?

13 **A. Yes, that is correct.**

14 Q. And the synthesis is the SP  
15 modification of the P&U route, this time dated  
16 May 28th, 1999; is that correct?

17 **A. Yes.**

18 Q. And to your recollection does that  
19 mean that this was the current process that  
20 Schwarz Pharma was pursuing with regards to  
21 synthesis of the enantiomeric prodrugs?

22 **A. Umm hmm.**

23 MR TRAINOR: Objection.

24 **A. Yes.**

25 MS CASSIDY: If you could turn back to

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1 PT 01932091?

2 A. Yes.

3 Q. Do you recognize the handwriting on  
4 this document?

5 A. Yes.

6 Q. Is that your handwriting?

7 A. Yes, it is.

8 Q. And in this you are referring in  
9 this handwritten section, you are referring to SPM  
10 8228, the statement that X is chloride; is that  
11 correct?

12 A. Yes.

13 Q. Does that mean that this was the  
14 hydrochloride salt that you were looking at?

15 A. Yes.

16 Q. And you state that this salt is  
17 amorphous and hysteresis; is that correct?

18 A. It is not precise. Once a salt is  
19 formed it is highly crystalline, but if it is  
20 exposed to moisture, traces of water, it is  
21 hysteresis, yes. Let me say it gives a syrup.

22 Q. And so you proposed looking at  
23 roughly 20 other salts to improve the  
24 physiochemical properties; is that correct?

25 A. Yes.

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1 Q. And did you have specific salts in  
2 mind already when you made this proposal?

3 A. No, not yet. That was on top of our  
4 salt screening programme at that time.

5 Q. Were you involved in the salt  
6 screening programme?

7 A. Yes.

8 Q. What was your role?

9 A. First of all I gave the co-workers  
10 the description for the initial experiments on a  
11 lab scale such as solvent concentrations, solvent  
12 mixtures in order to get precipitations matching  
13 time and temperatures.

14 Q. Anything else?

15 A. I involved a number of external  
16 CROs, among them the University of Wuppertal,  
17 Germany, and we needed simply manpower because  
18 it's laborious to make all those experiments.

19 Q. Anything else?

20 A. And there was a brief involvement of  
21 the University of Groningen in the Netherlands,  
22 Holland. That is also in order to make some  
23 experiments. And I told them which acids should  
24 be tested first, so the necessities or which assay  
25 should be used and with what are the solvents, and

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1 some of the reaction conditions also were given to  
2 the partners. They started the work for us.

3 Q. And which acids did you think should  
4 be tested first?

5 A. A large variety of inorganic acids,  
6 but also organic acids such as citric acid or  
7 tartaric risk acid, of course mendelic acid. And  
8 I remember I have to look at more than 100 acids.

9 Q. Right. I am going to hand you a  
10 document that will be marked as Meese Exhibit 30,  
11 bearing Bates numbers PT 01718486 through PT  
12 01718498.

13 (Exhibit 30 marked for identification)

14 A. Thank you.

15 Q. Dr Meese, do you understand these to  
16 be the minutes of the CMC sub team taken on  
17 October 8th, 1999?

18 A. Umm hmm.

19 Q. And did you attend this meeting?

20 A. Yes, I did.

21 Q. What does CMC sub team mean?

22 A. That means that the project was  
23 pretty far developed and this sub team takes care  
24 primarily of chemistry. Yes, it seems CMC is  
25 clear.

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1 Q. If you could turn to page PT  
2 01718494?

3 MR TRAINOR: 495?

4 MS CASSIDY: 494.

5 **A. Yes, okay.**

6 MS CASSIDY: And is it your  
7 understanding that as of September 30th, 1999 this  
8 SP modification of the P&U route was the current  
9 synthesis route that Shorts Pharma was following  
10 in the synthesis of their prodrugs salt?

11 **A. Yes, absolutely.**

12 MR TRAINOR: Objection.

13 **A. Because it has significant**  
14 **advantages over all alternatives. This was the**  
15 **way we made the product and enantiomers.**

16 MS CASSIDY: Dr Meese, I am going to  
17 hand you a document that will be marked as Meese  
18 Exhibit 31, a document which bears Bates numbers  
19 PT 01932079 through PT 01932081.

20 (Exhibit 31 marked for identification)

21 Dr Meese, have you seen this document  
22 before?

23 **A. I must have a look at that. I can't**  
24 **remember and I don't find my name on the paper,**  
25 **not as addressee or in a footnote. It looks like**

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1 a technical report from Mr -- Dr Arth.

2 Q. If you can look under section 2 do  
3 you see where it begins:

4 "By August 31st 1999 stable crystals of  
5 SPM 8224 hydrogen fumarate named SPM 8272 was  
6 available for the first time with a melting point  
7 of about 84 degrees Celsius."

8 A. Yes, that's right.

9 Q. And do you recall whether stable  
10 crystals of SPM 8224 had been formed -- strike  
11 that.

12 Do you recall whether prior to  
13 August 31st, 1999 any stable salt forms of  
14 festoterodine had been formed?

15 MR TRAINOR: Right now the question is  
16 just any stable salt forms?

17 MS CASSIDY: Any stable salt forms?

18 A. Yes, we made bromide and  
19 hydrochloride, monohydrate, at least those two  
20 besides the hydrogen fumarate here. This is all  
21 mentioned in the patent to stable salts.

22 MS CASSIDY: Earlier we discussed a salt  
23 screening programme, why is it necessary to  
24 conduct a salt screening programme?

25 MR TRAINOR: Objection.

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1           A. For chemical process and the  
2 pharmaceutical operation it is absolutely  
3 necessary to have stable salts which are  
4 chemically and thermally stable on the shelf and  
5 in the formulation of the drug product, and that's  
6 the compound is not allowed to be hydroscopic. It  
7 must be crystalline, highly crystalline. That is  
8 really a must. Therefore, we made much efforts to  
9 have success here in this field.

10           Q. Dr Meese, I am going to hand you an  
11 Exhibit marked as Meese Exhibit 32. This document  
12 bears Bates numbers PT 01931905 through PT  
13 01931917.

14           (Exhibit 32 marked for identification)

15           A. Thank you.

16           Q. Dr Meese, do you recognize these as  
17 the January 5th, 2000 meetings of the project team  
18 meeting for NCE incontinence?

19           A. It is 2000. Yes.

20           Q. And did you attend this meeting?

21           A. Yes, I did.

22           Q. And if you could please turn to page  
23 PT 01931909?

24           A. This one, yes. Okay.

25           Q. This attachment is titled: CMC

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1 update January 5th, 2000. Did you participate in  
2 the drafting of this document?

3 A. Yes. Yes.

4 Q. And at point bullet point 4 it  
5 states that:

6 "Alternative synthesis route from step 5  
7 to step 6 via amid showed reduced amount of  
8 impurities by increasing total yield."

9 Do you recall whether this alternative  
10 synthesis route was an alternative within the SP  
11 modification to the P&U route?

12 MR TRAINOR: Objection.

13 A. No, the Isotyrlic route is not shown  
14 here in this attachment. I am irritated that the  
15 synthetic scheme, the complete synthetic scheme  
16 with the numbers which are mentioned here step 5  
17 to 6 is not shown. That is unusual. Normally  
18 I attach the chemistry. I have problems to  
19 remember this actually paper because I am  
20 irritated that improvement steps should be  
21 demonstrated and documented. Yes, of course, we  
22 have it in Monheim in the archives.

23 MS CASSIDY: I am going to hand you a  
24 document which will be Meese Exhibit 33 bearing  
25 Bates numbers PT 01717920.

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1 (Exhibit 33 marked for identification)

2 Dr Meese, do you see your name in the to  
3 line of this e-mail?

4 A. Yes, I see my name.

5 Q. And this e-mail was sent to you from  
6 Andrea Schutz; is that correct?

7 A. That's right.

8 Q. What was Andrea Schutz's role in the  
9 development of festoterodine?

10 A. The -- once the final project,  
11 meeter or manager, after the pre-project has been  
12 finished the boss decided that this project will  
13 be a company project, as mentioned before, and as  
14 of that time she was the project leader and no  
15 longer Peter Ney stopped his activities on this  
16 field, or Christoph Arth, he was the intermediate  
17 manager for the sub team.

18 Q. If you look at the sentence  
19 beginning in the fourth line from the bottom, it  
20 states:

21 "This current route of synthesis is  
22 working well, therefore Claus Meese will leave the  
23 project team from now on."

24 What was your role in the festoterodine  
25 project after this e-mail dated June 8th, 2001?

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1           A. As internal political reasons.  
2           (speaking to counsel).

3           MR TRAINOR: If you understand and know.  
4           The question is what was your role after, so can  
5           you just answer that question?

6           A. The question was that we have some  
7           organizational changes at that time. Linda Hakes  
8           came to Schwarz Pharma and was responsible for the  
9           preclinical development and it was decided to  
10          involve our Company in Ireland much more strongly  
11          than before. At my role to answer on your  
12          specific question, should be an internal act as  
13          internal consultant for Schwarz Pharma and the  
14          project. There were several personnel changes in  
15          the following weeks and months.

16          Q. So -- sorry, were you finished? So  
17          after this date did your day-to-day involvement  
18          with the festoterodine project decrease?

19          A. Yes, that's true, and part of my  
20          work was done by another man, and I can't see him  
21          here. No, he is just missing. The rest of the  
22          people who work in the project team of  
23          festoterodine.

24          Q. Do you recall who that was?

25          A. Pardon?

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1 Q. Do you recall what his name was?

2 A. Yes, yes, Joerg Hamann. Dr Joerg  
3 Hamann, H-A-M-A-N-N.

4 MS CASSIDY: I think we have been going  
5 about an hour and I am at a good breaking point if  
6 you want to take a short break?

7 MR TRAINOR: Okay.

8 MS CASSIDY: Or break for the night.

9 THE VIDEOGRAPHER: Off-the-record at  
10 5.08.

11  
12 (Short Recess)

13 THE VIDEOGRAPHER: Back on the record at  
14 5.19.

15 MS CASSIDY: We will now break for the  
16 night and reconvene tomorrow morning.

17 THE VIDEOGRAPHER: This is the end of  
18 Tape Four and concludes Tape Four, Volume One of  
19 Dr Claus Meese's deposition.

20  
21 -----ooo-----  
22

23  
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CERTIFICATE OF DEPONENT

I, Claus Meese, hereby certify that I have read the foregoing pages of my deposition of testimony taken in these proceedings on Tuesday, 20th January 2015 and, with the exception of the changes listed on the next page and/or corrections, if any, find them to be a true and accurate transcription thereof.

Signed: .....

Name: Claus Meese

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CERTIFICATE OF COURT REPORTER

I, Kay Hendrick, an Accredited Court Reporter,  
hereby certify that the testimony of the witness,  
Claus Meese, in the foregoing transcript taken on  
Tuesday, 20th January, 2015 was recorded by me in  
machine shorthand and was thereafter transcribed  
by me; and that the foregoing transcript is a true  
and accurate verbatim record of the said  
testimony.

I further certify that I am not a relative,  
employee, counsel or financially involved with any  
of the parties to the within cause, nor am I an  
employee or relative of any counsel for the  
parties, nor am I in any way interested in the  
outcome of the within cause.

Signed: .....

KAY HENDRICK

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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PFIZER INC. and UCB PHARMA GMBH  
Plaintiffs

vs.  
C.V. No. 13-1110 (GMS)

ALKEM LABORATORIES LTD., CONSOLIDATED  
Et al.  
Defendants.  
-----

CONFIDENTIAL ATTORNEYS EYES ONLY  
Videotaped Deposition of Claus Meese  
Vol 2

Taken at the offices of:  
McDermott Will & Emery  
Avenue des Nerviens 9-31  
1040 Brussels

Wednesday, 21st January 2015  
At 9.36 a.m.

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

2

3       ON BEHALF OF PLAINTIFFS and THE WITNESS:

4                   WHITE & CASE LLP  
5                   1155 Avenue of the Americas  
6                   New York, New York 10036-2787  
7                   212.819.8255  
8                   JAMES S. TRAINOR, ESQ.  
9                   jtrainor@whitecase.com  
10                  JURGEN HASSA  
11                  jürgen.hassa@ucb.com

12       ON BEHALF OF DEFENDANT, APOTEX, INC.:

13                                   RAKOCZY MOLINO MAZZOCHI SIWIK LLP  
14                                   Six West Hubbard Street  
15                                   Suite 500  
16                                   Chicago, Illinois 60654  
17                                   312.527.2157  
18                                   BY PHONE: KEVIN BURKE

19       ON BEHALF OF DEFENDANTS, SANDOZ INC.

20                                   McDERMOTT WILL & EMERY  
21                                   227 West Monroe Street  
22                                   Chicago, Illinois 60606-5096  
23                                   312.984.5810  
24                                   slo@mwe.com  
25                                   WAN-SHON LO

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1 ON BEHALF OF DEFENDANTS, WOCKHARDT BIO AG and  
2 WOCKHARDT USA, LLC:

3 KNOBBE, MARTENS, OLSON & BEAR, LLP  
4 2040 Main Street  
5 14th Floor  
6 Irvine, California 92614  
7 949.760.0404  
8 KAREN CASSIDY, ESQ.  
9 karen.cassidy@knobbe.com

10 Also Present:

11 Kay Hendrick - Court Reporter  
12 Simon Rutson - Videographer  
13 Andrea Boyer - Interpreter  
14  
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E X H I B I T S

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1 Wednesday, 21st January 2015

2

3 THE VIDEOGRAPHER: This is the beginning  
4 of Tape One, Volume 2 and a continuation in the  
5 deposition of Dr Claus Meese. Dr Meese is still  
6 under oath from yesterday and we are on-the  
7 record.

8

DR CLAUD MEESE

9

having been duly Previously sworn,

10

testified as follows:

11

Examination by Ms Cassidy:

12

Q. Good morning, Dr Meese. Have you

13

discussed the content of your testimony with

14

anyone since this deposition was ended last night?

15

A. No, no.

16

Q. I am going to hand you a document

17

which will be marked as Meese Exhibit 34, bearing

18

Bates numbers PT 01742062 through PT 01742110.

19

(Exhibit 34 marked for identification)

20

Dr Meese, do you recognize that this is

21

a document from a festoterodine brainstorming

22

meeting held on September 12th, 2003. This is

23

part one of the meeting?

24

A. Yes.

25

Q. Did you attend this meeting?

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1           **A. Yes, I did.**

2           Q. And if you could turn to page PT  
3 01742064. In section 1.0 general introduction  
4 there are two bullet points. The first states  
5 that you are discussing improvements to the  
6 current festoterodine process?

7           **A. Yes.**

8           Q. Why was it believed that there were  
9 improvements needed to the current festoterodine  
10 process?

11           MR TRAINOR: Objection.

12           **A. We agreed that the process was too**  
13 **lengthy, too many steps and we also had the**  
14 **feeling that with not too much work significant**  
15 **improvements can be made.**

16           MS CASSIDY: And what was the concern  
17 with the process being too lengthy?

18           MR TRAINOR: Objection.

19           **A. The price of the by products**  
20 **substances.**

21           MR TRAINOR: By product substances?

22           THE INTERPRETER: Bulk drug substance  
23 was too high.

24           MR TRAINOR: I'm sorry.

25           **A. Was too high, the price of the bulk**

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1 drug substance was too high as compared to some  
2 competing compounds on the market so we wanted to  
3 reduce that.

4 MR TRAINOR: When you answer in English  
5 try to keep your voice up a little bit so she can  
6 hear you.

7 A. Okay.

8 MS CASSIDY: Were there any other  
9 concerns with the process being too lengthy?

10 A. Yes, there were some. In some steps  
11 there were safety concerns. There was one step  
12 where the reaction is extremely exothermic and  
13 this is on a large scale a risk, a risk of an  
14 explosion. We fully agreed on all points. It was  
15 a very nice brainstorming meeting.

16 Q. If you could turn to PT 01742066?

17 A. Yes.

18 Q. As of this meeting in September 2003  
19 is the process depicted on this page the current  
20 process that was being used?

21 A. Yes.

22 MR TRAINOR: Objection.

23 A. Yes.

24 MS CASSIDY: In this process can you  
25 tell me which step was the extremely exothermic

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1 reaction that had safety concerns?

2 MR TRAINOR: Objection.

3 A. Yes, they don't have simple numbers  
4 here. It is the process for SPM 7699 to SPM 7642.  
5 You see the third row of structures, if you see  
6 the scheme the left compound and the compound in  
7 the middle, that means that bromine, aromatic  
8 bromine compound converted into a Grignard  
9 intermediate and this is extremely reactive. This  
10 Grignard reacts with carbon dioxide or another  
11 carbon dioxide analogue to give the methyl ester  
12 which has the internal code SPM 7642. This is an  
13 extremely exothermic step.

14 MS CASSIDY: Do you recall which of the  
15 bulk drug substances were expensive and that you  
16 were trying to reduce costs on?

17 A. I don't think it is a singular  
18 reagent or intermediate or raw material. It is  
19 simply the problem is the number of steps. For  
20 industrial processes very short routes are wanted  
21 such as four or five, but not 11, that's too much.

22 Another point which was discussed on  
23 that excellent meeting is that it is a linear  
24 synthesis. This is always a problem. That means  
25 if we have a low yield at the beginning of the

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1 process this will have direct consequences for the  
2 yield, total yield of the final product. In  
3 industrial processes it's more favorable to have  
4 convergent synthesis. That means two products  
5 were connected to give another product which is  
6 very close to the final product, so any losses in  
7 yield can be compensated more easily.

8 Q. I am going to hand you a document  
9 that will be marked as Meese Exhibit 35, it bears  
10 Bates numbers PT 01742114 through PT 01742144.

11 (Exhibit 35 marked for identification)

12 Dr Meese, do you recognize this to be  
13 part two of the documents related to festoterodine  
14 brainstorming meeting held on September 12th,  
15 2003?

16 A. Yes, yes.

17 Q. If you could please turn to page PT  
18 01742124?

19 A. Yes.

20 Q. Actually make that PT 01742126. And  
21 in this section it appears that during this  
22 meeting you discussed alternative approaches to  
23 SPM 7605?

24 A. That's right. The scheme shown here  
25 is exactly the hazardous process which I mentioned

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1     **before.**

2                   Q.   Okay.  And if you can review the  
3     page you are on, the one ending in 2126 through  
4     the page ending in 2140?

5                   **A.   40?**

6                   MR TRAINOR:  She's asking that he looks  
7     through them.

8                   **A.   Sorry, I can't find it.**

9                   MS CASSIDY:  If it is easier we can walk  
10    through these one page at a time and it will be  
11    fairly quick on each page.  Why don't you turn to  
12    page PT 01742128?

13                   **A.   Yes.**

14                   MS CASSIDY:  And do you see the reaction  
15    labeled Scheme 9, it is the reaction at the top of  
16    the page, most of the page?

17                   **A.   Yes.**

18                   MS CASSIDY:  And was this proposed as an  
19    alternative approach to SPM 7605?

20                   **A.   Yes.**

21                   MR TRAINOR:  Objection.

22                   **A.   Yes, it has been discussed as an  
23    alternative, yes.**

24                   MS CASSIDY:  And if you could look back  
25    to page PT 01742118?

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1                   **A. Yes.**

2                   MS CASSIDY: Does Scheme 9 -- will  
3 Scheme 9 still include the intermediates SPM 7642,  
4 SPM 7604 and SPM 7605 -- let me break that up.  
5 Does Scheme 9 still include the intermediate SPM  
6 7642?

7                   MR TRAINOR: Objection. Can you clarify  
8 what you mean by "still include".

9                   MS CASSIDY: Does the intermediate with  
10 the structure of SPM 7642 appear in Scheme 9?

11                   MR TRAINOR: I think to answer this  
12 question he needs to reference the Scheme 9. Let  
13 me help him.

14                   MS CASSIDY: That's fine.

15                   MR TRAINOR: Do you remember the  
16 question?

17                   **A. No.**

18                   MS CASSIDY: Does the intermediate with  
19 the structure of SPM 7642 appear in Scheme 9 on  
20 page PT 01742128?

21                   MR TRAINOR: Objection.

22                   **A. Well, some structures are missing**  
23 **here in Scheme 9, so it is hard to answer. Some**  
24 **structures are identical to the survey scheme here**  
25 **but, you see this double arrow, that always means**

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1 there are potentially several steps in between  
2 which are not depicted. So I think this was a  
3 brainstorming meeting and these are some ideas  
4 which were discussed in the meeting. It is more  
5 important to look at the present process, which is  
6 shown in Scheme 1 at the beginning.

7 MS CASSIDY: And if you could turn the  
8 page to PT 01742130?

9 A. Yes.

10 MS CASSIDY: Which has -- is labeled  
11 Scheme 10 on it?

12 A. Yes.

13 MS CASSIDY: Was this also an  
14 alternative synthesis to make SPM 7605?

15 MR TRAINOR: Objection.

16 A. Yes, I remember the proposal. It is  
17 again an idea to supplement the critical Grignard  
18 process, which is Greek, a Grignard process, which  
19 is a very critical process because of the high  
20 reactivity of these intermediates, and the  
21 reaction is extremely exothermic, as I said. So  
22 it is unwanted to have these processes on an  
23 industrial scale. And this is an alternative but  
24 it was still during the brainstorming proposal,  
25 and I forget, this is not the place to discuss

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1 whether this is feasible or not.

2 Q. If you could turn to PT 01742132?

3 A. Okay.

4 Q. And there are two schemes on this  
5 page, Scheme 11 and Scheme 12, do you see the two  
6 schemes?

7 A. Yes, yes.

8 Q. Was Scheme 11 also proposed as an  
9 alternative synthesis of SPM 7605?

10 A. Yes, I remember this discussion, or  
11 this here --

12 Q. And if you look at --

13 A. Sorry.

14 Q. If you look at the arrows in  
15 Scheme 11, since these are not double arrows does  
16 that mean they are not intermediates that are not  
17 shown on this?

18 A. Yes. It took quite a long time.  
19 I like that scheme here, Scheme 11. It is my  
20 personal opinion. It is the attempt to introduce  
21 re-chirality and this step, less, of course, a  
22 good idea but the problem is that it is extremely  
23 difficult to make an antio-selective  
24 hydrogenations which are shown here. That means  
25 that you need a big team which works for, let me

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1 say, half a year or two years on this only step.  
2 That was clear to the team. In theory it's great.  
3 Yes. Chirality, that's okay.

4 And the process shown in Scheme 12 is  
5 addressed to the same problem chiral hydrogenation  
6 to introduce the chiral center in a more  
7 intelligent way. What we made was a resolution,  
8 that means primarily 50% of the material was going  
9 to be resolved as waste unless another step allows  
10 a resolution in order to recycle the waste which  
11 contains 50% of the r-enantiomer which is wanted.  
12 This is again a good idea, and I don't know who  
13 introduced this idea but it is again like  
14 Scheme 11, a process which requires basic work.  
15 And it was a result of this meeting that the  
16 Company was not willing to invest too much  
17 manpower and money into basic work.

18 MS CASSIDY: And if you turn the page to  
19 PT 01742134. Was Scheme 13 also an alternative to  
20 creating SPM 7605?

21 MR TRAINOR: Objection.

22 A. Yes, that's right. It is a simple  
23 idea because we have two reductive processes in  
24 the production of SPM 7605. The first step is the  
25 deep protection of the benzoyl protective groups

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1 of a compound shown in Scheme 13 on the left side.  
2 And the second step is the reduction of a methyl  
3 ester, and this might be done in one step with one  
4 reagent. That is what I suggest. That is more  
5 realistic than the other alternatives.

6 MS CASSIDY: And in Scheme 13 the single  
7 arrow again means that there are no missing  
8 intermediates?

9 A. That is right. So two steps with  
10 one reagent. Maybe switch to the next scheme,  
11 Scheme 14.

12 MS CASSIDY: Scheme 14, was that also an  
13 alternative --

14 A. Yes.

15 MS CASSIDY: -- synthesis to make SPM  
16 7605?

17 MR TRAINOR: Objection.

18 A. Well, it is a proposal to save at  
19 least one step.

20 MS CASSIDY: And if you could please  
21 turn to PT 01742136. And was Scheme 15 also an  
22 alternative synthesis of SPM 7605?

23 MR TRAINOR: Objection.

24 A. Scheme 15? Yes, it reminds me of  
25 the very, very early syntheses of

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1 3,3-diphenylpropylamine compounds which have been  
2 made in the 1960s by others. It is one of the  
3 many alternatives which might be checked, but --  
4 do you want me to comment on this? It is just to  
5 mention that I know this propyl was made. Yes.

6 MS CASSIDY: And if you turn the page to  
7 PT 01742138, there are two schemes. The first one  
8 is Scheme 16?

9 **A. Yes.**

10 MS CASSIDY: Was Scheme 16 also proposed  
11 as an alternative synthesis to make SPM 7605?

12 MR TRAINOR: Objection. Counsel, can  
13 you explain the relevance of this line of  
14 questioning? These are actions taken by the  
15 Company years after the Patents-in-Suit were  
16 filed. I really would appreciate an explanation  
17 of how any of this is relevant?

18 MS CASSIDY: We think it is relevant to  
19 whether they think this synthesis was -- the  
20 current synthesis in the patent was a good one and  
21 we wanted to see if they had some other  
22 alternatives. Just exploring his work on the  
23 synthesis.

24 MR TRAINOR: Objection. Go ahead.  
25 Could you please read back the question for him,

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1 Madam Translator?

2           A. Okay, yes, it's here. These are  
3 variances to introduce the isopropyl group at the  
4 amino group of the lower side chain, this by  
5 reductive elimination. Well, I won't go into  
6 details, it takes too much time. The isopropyl  
7 group, isopropyl, diisopropyl amino group in one  
8 step because the starting material is very cheap  
9 and available in unlimited amounts. I think  
10 I can't see any advantage.

11           MR TRAINOR: Diisopropyl, one word.  
12 D-I-S-O-P-R-O-P-Y-L.

13           MS CASSIDY: Was Scheme 17 also proposed  
14 as an alternative synthesis to make SPM 7605?

15           A. Yes.

16           MR TRAINOR: Objection. Just wait for  
17 me.

18           A. Okay, I wait.

19           MS CASSIDY: And if you turn to page PT  
20 01742140?

21           A. Yes, okay.

22           MS CASSIDY: There is a route labeled  
23 the ultra short lactone route. L-A-C-T-O-N-E?

24           A. Yes.

25           MS CASSIDY: Was the ultra short lactone

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1 route on this page also an alternative synthesis  
2 of SPM 7605?

3 **A. Yes.**

4 MR TRAINOR: Objection.

5 **A. Yes, it is a proposal I made several**  
6 **years ago. It is certainly one of the shortest**  
7 **routes, but again the opinion was the process is**  
8 **too far progress, we can not switch over to a**  
9 **completely new process.**

10 MS CASSIDY: And if you turn to page PT  
11 01742142?

12 **A. Yes, okay.**

13 MS CASSIDY: Above the conclusion there  
14 is a statement:

15 "Any of these routes if successful would  
16 provide a very short route to SPM 7605 and should  
17 be investigated thoroughly."

18 **A. Yes, I remember the summary.**

19 MS CASSIDY: And following this meeting  
20 did you believe that these routes would provide an  
21 improvement over the current 2000 --  
22 September 2003 route of synthesis of SPM 7605?

23 MR TRAINOR: Objection.

24 **A. Yes.**

25 MS CASSIDY: Dr Meese, if you could turn

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1 back to Exhibit 34?

2 **A. Yes.**

3 MS CASSIDY: And specifically to page PT  
4 01742090?

5 MR TRAINOR: Sorry, did you say 34?

6 MS CASSIDY: Exhibit 34, the part one of  
7 the 2003 meetings.

8 MR TRAINOR: Thank you.

9 MS CASSIDY: And if look under the  
10 section labeled: "Proposal (fumarate salt  
11 formation)."

12 And specifically bullet point five which  
13 states:

14 "Factors influencing crystallization  
15 need to be investigated, particularly with regard  
16 to the formation of amorphous versus crystalline  
17 material. Solubility curve to be established."

18 In the September 2003 process that was  
19 being discussed during these meetings were you  
20 still experiencing crystallization problems with  
21 that process?

22 **A. Yes.**

23 MR TRAINOR: Objection. Go ahead.

24 **A. Well, this is a summary what has**  
25 **been done. For instance, the individual steps**

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1 were discussed in detail and some critical point  
2 where some potential improvements which can be  
3 made.

4 MS CASSIDY: And during this meeting  
5 what factors influencing crystallization were  
6 investigated?

7 MR TRAINOR: Objection.

8 A. No, these are proposals, what should  
9 be done to get really a process improvement. That  
10 was the aim of the whole meeting. This is a  
11 summary of it.

12 MS CASSIDY: Were you involved in any  
13 later investigations of the factors influencing  
14 crystallization?

15 MR TRAINOR: Objection. Later than  
16 2003?

17 MS CASSIDY: Later than 2003.

18 A. No, at that time I was involved in  
19 other projects and the responsibility for the  
20 whole project in respect to chemistry was  
21 transferred to Dr Jorg Hamann, my deputy.

22 MS CASSIDY: During the September 2003  
23 meeting what, if any, potential factors  
24 influencing crystallization were discussed?

25 MR TRAINOR: Objection.

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1           A. I remember that all potential  
2 factors were discussed in detail. Many details  
3 are in these few lines and this proposal was to  
4 study this in detail. It was a brilliant meeting,  
5 I repeat that.

6           MS CASSIDY: In the manufacturing  
7 process at this time were seed crystals used to  
8 make festoterodine fumarate?

9           MR TRAINOR: Objection. And again this  
10 is 2003?

11          A. No, during the development of the  
12 industrial process we learned that the reaction to  
13 obtain crystalline material, final product, can be  
14 run without seed crystals, because you know we  
15 were expected to work under GMB conditions which  
16 restricts the use of foreign material in those  
17 processes. So we get crystalline material without  
18 seed crystals. That was a great advantage.

19          MS CASSIDY: At what point in the  
20 development process did you learn that the  
21 reaction could obtain the final product without  
22 seed crystals?

23          MR TRAINOR: Objection.

24          A. It's the last point, fumarate salt  
25 formation, the salt formation process.

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1 MS CASSIDY: Let me clarify, at what  
2 point in time during the development of the  
3 industrial process did you learn that you could  
4 develop, make the festoterodine fumarate  
5 formulation without the use of seed crystals?

6 MR TRAINOR: Objection.

7 A. During the development, the  
8 production of the final material a salt was made  
9 in several batches of about several kilograms and  
10 up to 40-80 kilogram, and we found that several  
11 factors influencing the crystallization process  
12 such as purity of starting material, reaction time  
13 concentration of the solvents, I think this was an  
14 empirical research for improvements which led to  
15 the final process which was discussed in 2003.

16 MS CASSIDY: What solvent system was  
17 used to crystalize festoterodine fumarate during  
18 the manufacturing process?

19 MR TRAINOR: During the manufacturing  
20 process? Objection.

21 A. Yes, it was methyl ethyl ketone  
22 which we abbreviate in the lab slang MEK, methyl  
23 ethyl ketone. This was the solvent system to  
24 dissolve the material which reacts together, and  
25 as an anti-solvent which makes the whole mixture

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1 less polar we used cyclohexane. We used both  
2 solvents due to laboratory experience and to  
3 toxicological process because traces of this  
4 compounds are critical. The toxicology to humans  
5 of both solvents is well known and investigated,  
6 and very low. So that was an advantage for the  
7 process.

8 THE INTERPRETER: What I said was methyl  
9 ethyl ketone, and I also said cyclohexane and I  
10 said that we had a term we used in the lab for  
11 methyl ethyl ketone which is MEK, M-E-K.

12 MS CASSIDY: Dr Meese, could you turn  
13 back in Exhibit 34 to PT 01742066?

14 A. Yes.

15 MS CASSIDY: And if you could just stay  
16 on that page I am going to hand you a document  
17 which will be marked as Meese Exhibit 36, a  
18 document bearing Bates numbers PT 01282901 through  
19 PT 01282930.

20 (Exhibit 36 marked for identification).

21 Dr Meese, this is a festoterodine due  
22 diligence covering October 2005 to February 2006.  
23 If you could please turn to PT 01282913?

24 MR TRAINOR: Just note for the record  
25 that I don't know how the Defendants can represent

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1 what this document is, it came from Schwarz's  
2 files. But you can proceed.

3 MS CASSIDY: I will clarify or represent  
4 that it is a document titled: The festoterodine  
5 technical Due Diligence from October 2005 to  
6 February 2006.

7 Do you see where it says Scheme 1:  
8 Summary of the Schwarz synthesis of festoterodine  
9 fumarate highlighting the isolated solid  
10 intermediates?

11 MR TRAINOR: And I just in addition,  
12 I am not waiving any other objections but I just  
13 want to note that this doesn't indicate that  
14 Dr Meese was at this meeting or had anything to do  
15 with this document. You have not established that  
16 he knows anything about this.

17 **A. No.**

18 MR TRAINOR: But with that objection,  
19 without waiving others you can proceed with the  
20 questioning.

21 **A. I never have seen this paper.**

22 MS CASSIDY: That's fine. I am not  
23 going to ask you about the contents of the  
24 meeting. Dr Meese, if you could look at Scheme 1  
25 in Exhibit -- in the festoterodine technical

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1 document?

2 **A. Yes.**

3 MS CASSIDY: And if you could please  
4 compare that to Exhibit 34, page PT 01742066,  
5 which states the introduction to the current  
6 process?

7 MR TRAINOR: Can you translate that,  
8 please?

9 MS CASSIDY: Do these two documents  
10 depict the same synthesis process?

11 MR TRAINOR: Objection.

12 **A. Yes, at the first glance but it**  
13 **should be checked very carefully. It looks at**  
14 **least similar or even identical, yes.**

15 MS CASSIDY: And, Dr Meese, I will note  
16 that in Scheme 1 on PT 01282913 the synthesis  
17 begins at SPM 7578, which appears to be the fourth  
18 structure on PT 01742066, if that helps you with  
19 your comparison?

20 MR TRAINOR: And the question?

21 MS CASSIDY: Same question, do these  
22 appear to be the same synthesis?

23 MR TRAINOR: Objection.

24 **A. I have to really take quite a lot of**  
25 **time to give an answer on this question because**

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1 I have to study each structure from both schemes  
2 and then I can answer. Parts of the process are  
3 identical but I can't say the whole process from  
4 the beginning to the final product is depicted  
5 here, because if you see the first row in the  
6 document.

7 MS CASSIDY: Which document?

8 A. Exhibit 36. There are many  
9 reactions summarized for the first two structures.  
10 As you see these are the different processes that  
11 take place above and below the reaction arrow in  
12 the first Scheme. Similarly, you have it here.  
13 Some of the reactions are actually identical.  
14 I can't see many basic differences in both  
15 processes. Yes.

16 MS CASSIDY: Thank you. You can set  
17 that aside.

18 A. Yes.

19 MS CASSIDY: And Dr Meese, if you can  
20 turn back to Exhibit 12 that we discussed  
21 yesterday?

22 MR TRAINOR: Do you want him to read the  
23 German one? Twelve is the translation, so maybe  
24 11.

25 MS CASSIDY: Eleven. Exhibit 11

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1 reflects your notes from your first meeting  
2 regarding this project held on August -- regarding  
3 the incontinence project held on August 28th,  
4 1997, correct?

5 **A. Yes, that's right.**

6 MS CASSIDY: And do you see in the  
7 center of the document there are four chemical  
8 structures depicted?

9 **A. Yes, that's right.**

10 MS CASSIDY: And the first one is an  
11 ester; is that correct?

12 **A. That is correct, yes.**

13 MS CASSIDY: And what was the purpose of  
14 drawing these chemical structures during this  
15 meeting?

16 MR TRAINOR: Objection.

17 **A. During that meeting with Bengt Sparf**  
18 **we discussed what can be modified within the**  
19 **molecule, the modification should be a cleaved**  
20 **able. It was already the concept of a prodrug**  
21 **synthesis at the very beginning, and there are**  
22 **many examples which clearly show that esters are**  
23 **under certain circumstances can be cleaved**  
24 **endogenously, in the organism, and the same is**  
25 **true for carbonates. And there are also examples**

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1 that certain ethers are also cleaved, which is an  
2 oxidative metabolism in contrast to the lipolysis  
3 or hydrolysis. So these are some proposals that  
4 are made on how we could start to get suitable  
5 derivatives.

6 MS CASSIDY: Why don't we take a short  
7 break?

8 **A. Yes.**

9 THE VIDEOGRAPHER: Off-the-record at  
10 10.33.

11 (Short Recess) brainstorming

12 THE VIDEOGRAPHER: Back on the record at  
13 10.53.

14 MS CASSIDY: Dr Meese, I am going to  
15 hand you a document which will be marked as Meese  
16 Exhibit 37, bearing Bates numbers PT 01931529  
17 through PT 01931531.

18 (Exhibit 37 marked for identification)

19 **A. Thank you.**

20 Q. Take a look at this document and let  
21 me know if you recognize it?

22 **A. Yes, I know that.**

23 Q. And if you could please turn to page  
24 PT 01931531?

25 **A. Yes.**

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1 Q. Is that your name and signature at  
2 the bottom right of the page?

3 A. Yes, it is.

4 Q. And Dr Meese, did you author this  
5 document?

6 A. Yes, together with Dr Peter Ney.

7 Q. If you could please turn back to  
8 page PT 01931529?

9 A. Yes. Umm hmm.

10 Q. The second paragraph lists several  
11 publications, do you see that?

12 A. Yes. Yes.

13 Q. Were these publications provided to  
14 you by Dr Sparf?

15 MR TRAINOR: Objection.

16 A. Maybe that he gave me one or two  
17 references, I can't remember. We make our own  
18 literature at patent research, of course.

19 MS CASSIDY: Dr Meese, why did you draft  
20 this document?

21 MR TRAINOR: Objection.

22 A. Well, Dr Linda Hakes came into the  
23 Company and got responsibility for research and  
24 development work in the preclinical area, and at  
25 the beginning of her work she asked me to briefly

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1 summarize the onset, the beginning of this  
2 project, and so I wrote this paper.

3 MS CASSIDY: And why was Dr Schact  
4 copied on this document?

5 MR TRAINOR: Objection. If you know.  
6 It is over here.

7 A. He was at that time the head of the  
8 Patent Department, Legal Department. Dietrich  
9 Schact. Yes, he gave some input.

10 MR TRAINOR: Hold on. Do not provide  
11 any communications that Dr Schact may have  
12 provided to you and your colleagues, any legal  
13 advice.

14 A. Okay.

15 MR TRAINOR: So I would instruct you not  
16 to provide any input that he provided.

17 A. Okay.

18 MR TRAINOR: Do you understand?

19 A. Okay.

20 MS CASSIDY: So Dr Schact was copied on  
21 this because he provided input on the document,  
22 and please just say yes or no without disclosing  
23 any information that you received from him?

24 MR TRAINOR: Objection.

25 A. Maybe he provided one or two

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1 references, so I think it is fair that he is  
2 informed.

3 MS CASSIDY: We have no further  
4 questions at this time.

5 A. Okay.

6 MR TRAINOR: No questions for the  
7 witness. Thank you.

8 THE VIDEOGRAPHER: Going off-the-record  
9 at 10.59. This is the end of Tape One, Volume 2  
10 and concludes the deposition of Dr Claus Meese.

11

12 -----OOO-----

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CERTIFICATE OF DEPONENT

I, Claus Meese, hereby certify that I have read the foregoing pages of my deposition of testimony taken in these proceedings on Wednesday, 21st January 2015 and, with the exception of the changes listed on the next page and/or corrections, if any, find them to be a true and accurate transcription thereof.

Signed: .....

Name: Claus Meese

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CERTIFICATE OF COURT REPORTER

I, Kay Hendrick, an Accredited Court Reporter, hereby certify that the testimony of the witness, Claus Meese, in the foregoing transcript taken on Wednesday, 21st January, 2015 was recorded by me in machine shorthand and was thereafter transcribed by me; and that the foregoing transcript is a true and accurate verbatim record of the said testimony.

I further certify that I am not a relative, employee, counsel or financially involved with any of the parties to the within cause, nor am I an employee or relative of any counsel for the parties, nor am I in any way interested in the outcome of the within cause.

Signed: .....

KAY HENDRICK

Dated: .....

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