


# Trial v05

## Designation List Report

 <b>Hellhammer, Brigitte</b>	<b>2013-09-11</b>
<b>Hellhammer, Brigitte</b>	<b>2013-09-12</b>

<a href="#">Our Designations</a>	<b>00:16:00</b>
<b>TOTAL RUN TIME</b>	<b>00:16:00</b>

-  Documents linked to video:
- PX5
  - PX74
  - PX146
  - PX210

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DESIGNATION	SOURCE	DURATION	ID
6:14 - 6:15	<b>Hellhammer, Brigitte 2013-09-11</b> 6:14 Q. Good morning, Doctor. 6:15 A. Good morning.	00:00:02	Hellhammer.1
7:03 - 8:06	<b>Hellhammer, Brigitte 2013-09-11</b> 7:03 Q. Brigitte, the first part of this 7:04 morning I just -- 7:05 A. Uh-huh. 7:06 Q. -- want to talk to you about your 7:07 background and your history with Ethicon, 7:08 Johnson & Johnson. Okay? 7:09 A. Okay. 7:10 I studied medicine in Hamburg 7:11 from 1976 until 1983. Subsequently, I worked 7:12 part time as the teacher at a nurse school, 7:13 because I had two small children. 7:14 And I started to work with 7:15 Ethicon in 1986. The position I had at the 7:16 time was manager of documentation, which meant 7:17 to collect literature for the R&D department 7:18 on the products and, later on, also write 7:19 literature reviews. 7:20 And about 1999 I also took over 7:21 other functions, such as project leader for -- 7:22 mainly for what we call the idea concept 7:23 phases of product development. 7:24 And I worked actively until 7:25 November 2010, when I left into a so-called 8:01 passive phase because I had decided to work 8:02 part time for the last three years, and I 8:03 worked full time for one year and a half and 8:04 then the rest I stayed at home. 8:05 And I officially left the 8:06 company end of April of 2012.	00:01:56	Hellhammer.2
52:13 - 52:22	<b>Hellhammer, Brigitte 2013-09-11</b> 52:13 Q. What other products were developed 52:14 through the TVT Star program or project? I 52:15 think you said the navigator -- 52:16 A. Uh-huh. 52:17 Q. -- there was a needle that was 52:18 developed.	00:00:27	Hellhammer.4

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DESIGNATION	SOURCE	DURATION	ID
	52:19 A. Yeah. As the next project we had 52:20 what we called the Gynemesh Vypro. That was a 52:21 mesh for pelvic floor based on the concept of 52:22 the so-called lightweight meshes.		
54:02 - 54:14	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:44	Hellhammer.5
	54:02 Q. And -- and you said that the 54:03 Gynemesh Vypro was a mesh that was developed 54:04 using the lightweight, large-pore concept; 54:05 correct? 54:06 A. Yes. 54:07 Q. And the lightweight, large-pore 54:08 concept was developed with the assistance of 54:09 the Aachen -- Aachen -- Aachen group; correct? 54:10 A. The original Vypro mesh for hernia 54:11 repair, yes, was developed in collaboration 54:12 with the Aachen group. 54:13 I was not part of that effort 54:14 at the time. That was earlier.		
59:05 - 59:21	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:35	Hellhammer.6
	59:05 Q. The -- the purpose of the 59:06 lightweight, large-pore concept -- 59:07 A. Uh-huh. 59:08 Q. -- was to help reduce the foreign 59:09 body material that would be left behind in a 59:10 patient's body. 59:11 A. Yes, I agree. 59:12 Q. Because what we're talking about 59:13 here is -- 59:14 A. To increase patient comfort. 59:15 Q. Right. 59:16 A. Uh-huh. 59:17 Q. Because what we're talking about 59:18 here is medical devices that would be 59:19 implanted in a human body for the remainder of 59:20 that person's life. 59:21 A. Yes. Uh-huh.		
95:08 - 95:21	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:46	Hellhammer.14
	95:08 And you understand, don't you, 95:09 as a person who worked in the R&D department, 95:10 that the Prolene mesh that was contained		

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	95:11 within the TVT product line --		
	95:12 A. Uh-huh.		
	95:13 Q. -- is the old-construction mesh		
	95:14 that was originally construction for hernia		
	95:15 repair back in 1975.		
	95:16 A. I agree, yes, obviously, from what		
	95:17 you showed me. I'm not sure if -- because I		
	95:18 was not involved, obviously, in -- in that		
	95:19 development, that the Prolene mesh was		
	95:20 specifically developed for hernia repair		
	95:21 rather than for soft tissue reinforcement.		
107:23 - 108:03	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:16	Hellhammer.15
	107:23 Q. And so that's one of the points		
	107:24 you bring up is a -- is a good point, weight,		
	107:25 and pore size are factors that you look at		
	108:01 and -- and maybe the pore size, in your		
	108:02 opinion, is more important than the actual		
	108:03 weight of the mesh.		
108:05 - 108:10	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:24	Hellhammer.16
	108:05 THE WITNESS: Well, for me,		
	108:06 yes, I agree with pore size because,		
	108:07 you know, it was our philosophy that		
	108:08 with the pore size you have the tissue		
	108:09 incorporation, as compared to		
	108:10 encapsulation.		
134:22 - 135:02	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:22	Hellhammer.18
	134:22 Q. And the reason you adopted the		
	134:23 Ultrapro concept, lightweight, large-pore		
	134:24 concept, for pelvic floor was to reduce the		
	134:25 foreign body response by creating a larger		
	135:01 pore so there would be healthier tissue		
	135:02 integration.		
135:05 - 135:07	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:02	Hellhammer.19
	135:05 Q. And there was a number of reasons.		
	135:06 I know there was more than that.		
	135:07 A. Yes.		
146:20 - 146:24	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:17	Hellhammer.20
	146:20 Q. You worked on the Prolift+M. And		
	146:21 both of those projects, one for hernia and one		


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DESIGNATION	SOURCE	DURATION	ID
	146:22 for pelvic floor, adopted the large-weight or 146:23 large-pore concept and -- and the -- 146:24 A. I agreed to that, yes.		
156:15 - 156:23	<b>Hellhammer, Brigitte 2013-09-11</b> 156:15 Based on the Aachen 156:16 classification, at least, the Prolene mesh in 156:17 TVT is heavyweight. 156:18 A. Yes. 156:19 Q. Okay. And the same mesh has been 156:20 used, same heavyweight mesh, has been used in 156:21 all of the TVT products, according to this 156:22 document. 156:23 A. From what we see, yes.	00:00:24	Hellhammer.25
183:18 - 183:24	<b>Hellhammer, Brigitte 2013-09-11</b> 183:18 Q. Well, you had an opinion before 183:19 today's deposition, when you worked for 183:20 Ethicon, you understood that -- that certain 183:21 meshes or mesh materials, the way -- the way 183:22 that they were constructed could elicit a 183:23 greater foreign body response -- 183:24 A. Yes.	00:00:18	Hellhammer.31
202:20 - 203:02	<b>Hellhammer, Brigitte 2013-09-11</b> 202:20 Q. So -- and I appreciate that you 202:21 were with the company for a long time and the 202:22 company is defended in this case but, I mean, 202:23 you agree with me, based on your history and 202:24 through the work of Dr. Klosterhalfen and 202:25 Klinge, that this fibrotic bridging was found 203:01 to cause a number of adverse events, including 203:02 things like chronic pain; right?	00:00:23	Hellhammer.38
203:04 - 203:07	<b>Hellhammer, Brigitte 2013-09-11</b> 203:04 THE WITNESS: I agree that, 203:05 according to their theory, the meshes 203:06 with smaller pore led to fibrotic 203:07 bridging.	00:00:11	Hellhammer.39
211:18 - 211:19	<b>Hellhammer, Brigitte 2013-09-11</b> 211:18 Q. Polypropylene will shrink 30 to 50 211:19 percent; right?	00:00:07	Hellhammer.42
211:21 - 212:10	<b>Hellhammer, Brigitte 2013-09-11</b>	00:00:28	Hellhammer.43

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DESIGNATION	SOURCE	DURATION	ID
	<p>211:21 THE WITNESS: Well, it -- the</p> <p>211:22 findings that are out there -- and</p> <p>211:23 they come from the Aachen group -- are</p> <p>211:24 that the polypropylene meshes with the</p> <p>211:25 smaller pore size shrink by a certain</p> <p>212:01 amount and then there is a difference</p> <p>212:02 between the shrinkage between -- of</p> <p>212:03 the -- these meshes with the -- the</p> <p>212:04 larger-pore meshes.</p> <p>212:05 BY MR. THORNBURGH:</p> <p>212:06 Q. The larger-pore meshes won't</p> <p>212:07 shrink as much; right?</p> <p>212:08 A. Yes. But -- but they still do --</p> <p>212:09 Q. They still shrink.</p> <p>212:10 A. -- do shrink. Yes, they do.</p>		Hellhammer.43
218:15 - 218:16	<p><b>Hellhammer, Brigitte 2013-09-11</b></p> <p> PX146.2</p> <p>218:15 Q. I've marked -- this has been</p> <p>218:16 premarked as Exhibit T-1240.</p>	00:00:04	Hellhammer.44
218:19 - 219:03	<p><b>Hellhammer, Brigitte 2013-09-11</b></p> <p> PX146.2.1</p> <p>218:19 Q. And you see this is a -- a</p> <p>218:20 presentation by Boris Batke from the research</p> <p>218:21 and development department.</p> <p>218:22 That's your department; right?</p> <p>218:23 A. Uh-huh.</p> <p>218:24 Q. And it says, "The (clinical)</p> <p>218:25 argument of lightweight mesh in abdominal</p> <p>219:01 surgery"; right?</p> <p>219:02 See that?</p> <p>219:03 A. Yes, I see it.</p>	00:00:26	Hellhammer.45
227:03 - 227:11	<p><b>Hellhammer, Brigitte 2013-09-11</b></p> <p> PX146.5.1</p> <p>227:03 Q. So if you look at Page 4,</p> <p>227:04 it says "Polypropylene Mesh, Small pore size";</p> <p>227:05 right?</p> <p>227:06 A. Uh-huh.</p> <p>227:07 Q. It says less -- less than 1</p> <p>227:08 millimeter. This is --</p> <p>227:09 A. Yes.</p> <p>227:10 Q. -- discussing polypropylene mesh.</p> <p>227:11 A. Uh-huh.</p>	00:00:11	Hellhammer.46

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DESIGNATION	SOURCE	DURATION	ID
228:14 - 228:18	<b>Hellhammer, Brigitte 2013-09-11</b> 228:14 So you understand that this 228:15 document, the person in your department was 228:16 calling Prolene mesh, was defining Prolene 228:17 mesh as less than 1 millimeter and 228:18 heavyweight.	00:00:14	Hellhammer.47
228:22 - 228:22	<b>Hellhammer, Brigitte 2013-09-11</b> 228:22 A. Yes. Yes.	00:00:01	Hellhammer.48
238:10 - 239:01	<b>Hellhammer, Brigitte 2013-09-11</b> 238:10 Q. Dr. Hellhammer, before we went off 238:11 the record, we were talking about Slide 5 -- 238:12 A. Uh-huh. 238:13 Q. -- from Exhibit 1240 and we were  PX146.6.2 238:14 talking about the experience with heavyweight 238:15 meshes. 238:16 And what we see here is that 238:17 the experience with heavyweight meshes was 238:18 known to Ethicon; right? 238:19 A. Uh-huh. 238:20 Q. And the heavyweight meshes were 238:21 associated with -- associated with, according 238:22 to this slide and according to what we've seen 238:23 with the lightweight, large-pore concept,  PX146.6.1 238:24 associated with excessive foreign body 238:25 reaction; right? 239:01 A. Uh-huh.	00:00:46	Hellhammer.49
239:04 - 239:21	<b>Hellhammer, Brigitte 2013-09-11</b>  PX146.6.3 239:04 Q. Chronic inflammation; right? 239:05 Right? 239:06 A. On the microscopic level. I want 239:07 to make sure that this is clearly understood. 239:08 Because inflammation, sometimes you talk and 239:09 you think you have a lot of redness and bulge, 239:10 et cetera. So this is chronic inflammation -- 239:11 Q. All right. And -- 239:12 A. -- on the microscopic level. 239:13 Uh-huh. 239:14 Q. Right. And we -- and we -- we 239:15 learned about these -- this experience from 239:16 the explants of meshes that were evaluated by	00:00:53	Hellhammer.50

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DESIGNATION	SOURCE	DURATION	ID
	239:17 Dr. Klinge and Klosterhalfen in their -- 239:18 through their work with Ethicon. 239:19 A. Well, yes, I agree in one part, 239:20 but I think additional -- additionally, from 239:21 experimental studies.		
 Clear			
314:07 - 314:10	<b>Hellhammer, Brigitte 2013-09-11</b> 314:07 Q. But yet Ethicon continued to use 314:08 heavyweight polypropylene mesh in women's 314:09 pelvises, in their -- in and around their 314:10 vagina; right?	00:00:12	Hellhammer.61
314:12 - 314:13	<b>Hellhammer, Brigitte 2013-09-11</b> 314:12 THE WITNESS: Yes, we continued 314:13 to use these products.	00:00:03	Hellhammer.62
339:05 - 339:08	<b>Hellhammer, Brigitte 2013-09-11</b> 339:05 MR. THORNBURGH: I'll mark as 339:06 Exhibit 4002 a document written by you 339:07 called "Meshes in Pelvic Floor 339:08 Repair."	00:00:09	Hellhammer.73
 PX5.1.1			
339:20 - 340:01	<b>Hellhammer, Brigitte 2013-09-11</b> 339:20 Q. This says, the front page, says 339:21 prepared by you; correct? 339:22 A. Yes. 339:23 Q. And the date of this document is, 339:24 if you look on the next page, June 6th, 2000. 339:25 See that? 340:01 A. Yes, I see that.	00:00:19	Hellhammer.74
 PX5.2.1			
 Clear			
342:17 - 343:04	<b>Hellhammer, Brigitte 2013-09-11</b> 342:17 Q. Overall, revision and removal rate 342:18 among 961 synthetic suburethral slings was 7.3 342:19 percent; right? 342:20 A. Uh-huh. 342:21 Q. And you say, removal -- revision 342:22 and removal; right? 342:23 A. Yes, revision and removal. 342:24 Q. Because -- because revision may 342:25 be -- may be, you've described it earlier, may 343:01 be clipping or -- or revising the tape in some 343:02 way but not actually removing the tape totally 343:03 from the implant site; right?	00:00:34	Hellhammer.75
 PX5.5.1			



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DESIGNATION	SOURCE	DURATION	ID
	 Clear		
539:18 - 539:23	343:04 A. Right. <b>Hellhammer, Brigitte 2013-09-12</b>	00:00:20	Hellhammer.88
	539:18 Q. you also met with people doing 539:19 pelvic floor repair who described to you that 539:20 one of the worst adverse events that their 539:21 patients could experience is chronic pain 539:22 because it was too difficult to treat that 539:23 problem; right?		
539:25 - 540:02	<b>Hellhammer, Brigitte 2013-09-12</b>	00:00:05	Hellhammer.89
	539:25 THE WITNESS: I agree with you 540:01 that was discussed at the expert 540:02 meeting.		
540:20 - 541:13	<b>Hellhammer, Brigitte 2013-09-12</b>	00:01:02	Hellhammer.90
	540:20 Q. Because I asked you if you had an 540:21 understanding that these heavyweight, 540:22 small-pore meshes could be associated with 540:23 chronic pain and you said yes, in hernia 540:24 repair, but -- and -- and you were suggesting 540:25 that you didn't have that understanding for 541:01 pelvic floor repairs. 541:02 A. Yeah. I agree I missed the point. 541:03 I saw -- I heard about it at the meeting with 541:04 the pelvic floor experts, yes. 541:05 Q. And those are experts that were 541:06 actually in the field treating women with 541:07 meshes, some of them being small-pore, 541:08 heavyweight meshes, who had expressed concerns 541:09 that those -- that that type of mesh was 541:10 causing chronic pain in women; right? 541:11 A. Right. But what I recall is 541:12 that -- that they saw that -- that that was a 541:13 concern to them.		
602:03 - 602:06	<b>Hellhammer, Brigitte 2013-09-12</b>	00:00:15	Hellhammer.91
	602:03 Q. There's not a lighter-weight mesh 602:04 than the 6-mil polypropylene mesh that's -- 602:05 that has been used since the 1990s in the TVT 602:06 products; right?		
602:08 - 602:11	<b>Hellhammer, Brigitte 2013-09-12</b>	00:00:10	Hellhammer.92
	602:08 THE WITNESS: Well, during the		

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DESIGNATION	SOURCE	DURATION	ID
	602:09 time I was at Ethicon, that was the 602:10 product, yes. I can't say what 602:11 happened afterwards.		
602:13 - 602:20	<b>Hellhammer, Brigitte 2013-09-12</b> 602:13 Q. And the reason why -- why 602:14 lightweight meshes were deemed to be more 602:15 appropriate for implant -- implantable medical 602:16 devices -- 602:17 A. Uh-huh. 602:18 Q. -- was because -- because of the 602:19 phenomena that you wrote about, which was mesh 602:20 shrinkage; right?	00:00:18	Hellhammer.93
602:23 - 603:06	<b>Hellhammer, Brigitte 2013-09-12</b> 602:23 Q. That compared to Ultrapro, 602:24 polypropylene mesh -- heavyweight 602:25 polypropylene meshes shrunk. 603:01 A. Well -- well, they -- they were 603:02 compressed and the scar formation led to, you 603:03 know, a smaller surface area compared to 603:04 the -- to the lightweight -- 603:05 Q. And then -- 603:06 A. -- macroporous meshes.	00:00:22	Hellhammer.94
605:23 - 605:25	<b>Hellhammer, Brigitte 2013-09-12</b> 605:23 Q. Do you know who Kerstin Spsychaj 605:24 is? 605:25 A. Kerstin Spsychaj, yes.	00:00:06	Hellhammer.95
606:07 - 606:12	<b>Hellhammer, Brigitte 2013-09-12</b> 606:07 Q. And Miss Spsychaj was a colleague 606:08 of yours? 606:09 A. Yes. 606:10 Q. And what was -- she was also at 606:11 Ethicon R&D; right? 606:12 A. She was at Ethicon R&D, right.	00:00:11	Hellhammer.96
606:13 - 606:14  PX74.1	<b>Hellhammer, Brigitte 2013-09-12</b> 606:13 Q. Handing you what's been marked as 606:14 Exhibit Number 410 (sic), do you remember Dr.	00:00:04	Hellhammer.107
606:14 - 606:18  PX74.1.1	<b>Hellhammer, Brigitte 2013-09-12</b> 606:14 Exhibit Number 410 (sic), do you remember Dr. 606:15 Spsychaj giving a presentation during the	00:00:09	Hellhammer.108

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DESIGNATION	SOURCE	DURATION	ID
	606:16 expert meeting -- 606:17 A. Yes. 606:18 Q. -- one of the expert meetings?		
608:11 - 608:13  PX74.1.2	<b>Hellhammer, Brigitte 2013-09-12</b> 608:11 Q. So she says, factors related to 608:12 mesh shrinkage, she says, mesh material, mesh 608:13 weight and mesh shape; right?	00:00:06	Hellhammer.97
608:15 - 608:25   Clear	<b>Hellhammer, Brigitte 2013-09-12</b> 608:15 THE WITNESS: Yes, that's what 608:16 she says. 608:17 BY MR. THORNBURGH: 608:18 Q. There's no doubt in your mind that 608:19 those -- those factors of the mesh design 608:20 factor into the potentiation of a mesh 608:21 shrinkage; correct? 608:22 A. From the evidence that she 608:23 collected from the literature and from what we 608:24 know from the earlier work, yes, I -- I think 608:25 these -- these are the factors.	00:00:34	Hellhammer.98
615:20 - 615:23  PX210.2.1	<b>Hellhammer, Brigitte 2013-09-12</b> 615:20 Q. It says, in pelvic floor surgery 615:21 shrinkage seems to be more important than in 615:22 hernia surgery; right? 615:23 A. That's what it says, yes.	00:00:13	Hellhammer.99
618:22 - 619:03	<b>Hellhammer, Brigitte 2013-09-12</b> 618:22 Q. It's certainly not far-fetched to 618:23 believe that shrinkage in the woman's pelvis 618:24 was probably a more important issue for 618:25 physicians and for patients than in hernia 619:01 repair; right? 619:02 A. That's what they obviously said, 619:03 yes.	00:00:20	Hellhammer.100
623:13 - 623:17  PX210.2.2   Clear	<b>Hellhammer, Brigitte 2013-09-12</b> 623:13 Q. And Dr. Cosson says, polypropylene 623:14 meshes might not be improvable in terms of 623:15 shrinkage. We may need a completely new 623:16 material. Right? 623:17 A. That's what I see, yes.	00:00:15	Hellhammer.101

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Documents linked to video:

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