

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

**TAPENTADOL LITIGATIONS**

2:13-cv-04507-CCC-MF  
2:13-cv-06929-CCC-MF  
2:13-cv-07803-CCC-MF  
2:13-cv-03941-CCC-MF  
2:13-cv-04617-CCC-MF

Hon. Claire C. Cecchi

JANSSEN PHARMACEUTICALS INC.  
and GRÜNENTHAL GMBH,

Plaintiffs,

v.

ACTAVIS ELIZABETH LLC et al.

Defendants.

**Materials for 30(b)(6)**  
**Deposition of Dr. Ulrike Struck**



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**Dr. Struck's Rule 30(b)(6) Responses to Topics for Deposition of Grünenthal, May 8, 2015**

I have been asked to investigate and provide general deposition testimony regarding topic nos. 1, 2, 3, 5, 6, 7, 9, 10, 11, 12, 14, 15, 16, 20, 21, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 34, 35, 36, 37, 38, 39, and 45, as amended in Grünenthal's Responses to Defendants' Notice of Deposition. In providing the following answers to the topics I have been asked to investigate, I relied upon my own recollections, knowledge, and experience, my review of thousands of pages of documents, and the information I obtained from interviews with the following people:

- Helmut Buschmann (inventor on tapentadol and related compound patent and polymorph patent): Topics 1, 2, 5, 6, 9, 10, 11, 12, 14, 15, 16, 20, 21, 22, 25, 26, 27, 28, 29, 30, 34, 36, 37, 38, and 45.
- Thomas Christoph (inventor on polyneuropathic pain patent): Topics 3, 7, 10, 11, 12, 14, 15, 16, and 45
- Andreas Fischer (inventor on polymorph patent): Topics 2, 6, 20, 21, 25, 26, 27, 28, 29, 30, 34, 35, 36, 37, 38, and 39.
- Carsten Griebel (Process Development Department): Topics 31 and 32
- Michael Gruss (inventor on polymorph patent): Topics 2, 6, 20, 21, 23, 25, 26, 27, 28, 29, 30, 34, 35, 36, 37, 38, and 39.
- Edmund Heidenthal: Topic 23
- Kurt Hellfeldt (Grünenthal in-house attorney): Topics 5, 6, and 7
- Babette Koegel (inventor on polyneuropathic pain patent) Topics 3, 7, 10, 11, 12, 14, 15, and 16
- Alexander Kraus: Topics 22, 23, and 45
- Regina Kleinert: Topics 3, 10, 12, 14, 15, 16, 22, and 23
- Dagmar Lischke (inventor on polymorph patent): Topics 2, 6, 20, 21, 25, 26, 27, 28, 29, 30, 32, 34, and 35
- Murielle Méen (inventor on polyneuropathic pain patent): Topic 3, 7, 10, 12, 14, 15, and 16
- Marita Mueller (chemist who repeated Ex. 25 of tapentadol and related compounds patent): Topics 20, 21, 29, 30, 31, and 32
- Ralf Stowasser (Grünenthal in-house attorney): Topics 5, 6, and 7
- Oswald Zimmer (Process Development Department): Topics 31 and 32

Based on the information reasonably available to and appreciated by me from these sources,

I provide the answers below.

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	<b>Amended Topic</b>
1	<b>Conception and/or reduction to practice</b> of the inventions of the asserted claims of the <b>RE593</b> Patent
2	<b>Conception and/or reduction to practice</b> of the inventions of the asserted claims of the <b>'364</b> patent
3	<b>Conception and/or reduction to practice</b> of the inventions of the asserted claims of the <b>'130</b> patent
5	Prosecution of the <b>'593</b> and <b>'737</b> patents (tapentadol and related structures)
6	Prosecution of the <b>'364</b> patent (polymorph Form A)
7	Prosecution of the <b>'130</b> patent (polyneuropathic pain)
9	Preparation of tapentadol hydrochloride that was the basis for <b>Example 25</b> of the <b>'593</b> and <b>'737</b> patents and related analytical analyses
21	Practice of <b>Example 25</b> of U.S. Patent No. 6,248,737, U.S. Patent No. 6,344,558, and European Patent No. EP 0 693 475 B1 produces Form B of tapentadol hydrochloride
29	Identity of the crystalline form of tapentadol hydrochloride produced by the procedure described in <b>example 25</b> of U.S. Patent No. 6,248,737 and EP 693 475 B1
30	Procedure described in <b>example 25</b> of U.S. Patent No. 6,248,737 and EP 693 475 B1 and Marita Mueller's replication of that procedure
10 12 14 15 16	Grünenthal's decision to pursue tapentadol hydrochloride as a drug candidate
11	"In vitro models of pain" used at Grünenthal to test tapentadol hydrochloride
20	Examples, Figures, and Tables disclosed in the specification of the <b>'364</b> patent
22	(1) Grünenthal's <b>decision to grant an exclusive license</b> regarding pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States and (2) <b>payments received</b> pursuant to that license agreement
23	(1) Grünenthal's <b>decision to grant an exclusive license</b> regarding pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States; (2) <b>payments received</b> pursuant to that license agreement; and (3) Grünenthal's practice of requiring <b>confidentiality provisions</b> in contracts with third parties performing work for Grünenthal and/or consulting with Grünenthal
25	<b>Identity of crystalline forms</b> of tapentadol hydrochloride known to Grünenthal

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26	Examples of conditions under which crystalline Form A and/or Form B of tapentadol hydrochloride may <b>convert into another crystalline or non-crystalline form</b> of tapentadol hydrochloride
27	Examples of properties of crystalline Form A
28	Examples of properties of crystalline Form B
31	Whether <b>samples</b> of GB-Bu322-1-1, GB-Bu322-1-2, GB-Bu322-1-3, GB-Bu322-2-1, and PG1026-001-1-1 can be presently located at Grünenthal
32	(1) Grünenthal's process development department's implementation in <b>2010</b> of <b>regulations</b> in Germany that deemed tapentadol to be a <b>controlled substance</b> with respect to the storage of samples of tapentadol hydrochloride previously kept in the process development department and (2) the relevant Grünenthal protocol governing the expiration of the <b>reference standard</b> for Form B of tapentadol hydrochloride
34	Communication process between Grünenthal and <b>SSCI</b> on SSCI's work for Grünenthal on the polymorph screen of tapentadol hydrochloride
35	Final reports received from <b>SSCI</b> on the polymorph screen of tapentadol hydrochloride, the single crystal structure analysis of CG5503, the solubility study of CG5503 Forms A and B, and the moisture sorption/desorption analysis of CG5503 Form B performed for Grünenthal
36	Communication process between Grünenthal and <b>F&amp;E Analytik</b> regarding F&E Analytik's work for Grünenthal on the single crystal structure determination of tapentadol hydrochloride and the powder diffraction determination of BN200
37	Grünenthal Report No. FE-AC 513 - Crystal Structure of BN200 and Grünenthal Report No. FE-AC 514 - Powder Diffraction Determination of BN200
38	Communication process between Grünenthal and <b>Crystallics BV</b> regarding Crystallics BV's work for Grünenthal on the crystallization optimization of tapentadol hydrochloride
39	<b>Crystallics BV</b> 's final report for Grünenthal on the crystallization optimization for tapentadol hydrochloride
45	The following for the RE593 patent, '364 patent, and/or '130 patent: (1) unexpected results; (2) failure of others; (3) commercial success; and (4) praise for the invention



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