UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES LIMITED,
Petitioners,

v.

UCB PHARMA GMBH,
Patent Owner.

Case Nos. IPR2016-00510; IPR2016-00512; IPR2016-00514; IPR2016-00516; IPR2016-00517
Patent Nos. 6,858,650; 7,384,980; 7,855,230; 8,338,478; 7,985,772

DECLARATION OF CLAUS O. MEESE, Ph.D.

1. I, Dr. Claus Meese, submit this Declaration on behalf of UCB Pharma GMBH ("UCB"), in support of its Patent Owner Response in the above-referenced *Inter Partes* Reviews.
2. I am the named inventor of the inventions claimed in United States Patent No. 6,858,650 (the "'650 patent"). I am a named co-inventor of inventions claimed in United States Patent Nos. 7,384,980; 7,855,230; 7,985,772; and 8,338,478.
3. I testified at trial in *Pfizer Inc. v. Sandoz Inc.*, C.A. No. 13-1110 (GMS) (D. Del.). My testimony from the transcript of the proceedings in that trial is of record in this *inter partes* review. (See Ex. 2006 at 43:8 – 100:21.)
4. I am a German national and have always resided in Germany. Presently, I reside in Monheim, Germany.
5. I am an organic chemist, having earned both a diploma and Ph.D. from the University of Hamburg, where I studied pharmaceutical chemistry and pharmacy.
6. I was employed as a chemist and head of the Chemistry Department at the UCB predecessor, Schwarz Pharma AG ("Schwarz"), in Monheim, Germany, from 1993 until 2008, when I retired from the company.
7. Beginning in 1997, I was involved in a research and development project at Schwarz that resulted in the invention of the compound, fesoterodine

fumarate (the "Project") that today is the active ingredient in a drug marketed around the world for the treatment of overactive bladder.

8. My role in the Project was as leader of chemical development, and my responsibilities included the design, synthesis, and testing of candidate prodrugs of (R)-2-(3-(diisopropylamino)-1-phenylpropyl-4-(hydroxymethyl)phenol ("5-HMT") and later, the design, synthesis, and testing of salt forms of these candidate prodrugs, including the fumarate salt of fesoterodine. All such synthesis and testing was performed either by me or by others involved in the Project working at my direction.

9. Cited in this Declaration are certain Schwarz records reflecting the state of the Project as of the date of the respective documents. These records are in the form of internal reports from my chemistry department or meeting minutes from meetings of the Project Team. These records are representative of records ordinarily made and kept for all research and development projects undertaken at Schwarz during my time with the company. To the best of my knowledge, such documents referred to and cited to in this Declaration are true and correct copies of such Schwarz company records.

10. By February 1998, I had synthesized or directed the synthesis of at least 22 racemic 5-HMT prodrug candidates, including fesoterodine. (See Chemical Development Plan of 2/20/98 (Ex. 2094).) These candidates were identified in laboratory records by their benzyl-side/phenyl-side

substitution from the 5-HMT chemical structure, as well as by an "SPM" laboratory code number. (See id.; see also Timetable (Exhibit 2095) at 5.) For example, racemic fesoterodine was identified in Project records both as "HO/OiBut" and as "SPM 7504." (See Exhibits 2094 and 2095.)

11. By August 1998, I, or those at my direction, had synthesized racemic fesoterodine in the form of a hydrochloride salt, which is referred to in the Project records as "SPM 7527." (See Minutes of 9/10/98 Mtg. (Ex. 2096) at 9; Ex.2095 at 5.)

12. By February 1999, I, or those at my direction, had synthesized chiral (R-(+)) 5-HMT prodrug candidates, including the R-enantiomer of fesoterodine. (See Chem. Dev. Plan of 2/24/99 (Ex. 2097).) The free base form of R-enantiomer of fesoterodine is referred to in Project records as "SPM 8224." (See Lab. Jnl. of 8/19/99 (Ex. 2098).) At that time, my colleagues and I had already observed the difficulty in preparing stable, crystalline, and non-hygroscopic salts of these chiral 5-HMT prodrug candidates. (See Ex. 2097.)

13. By May 1999, our Project Team at Schwarz has identified the R-enantiomer of fesoterodine as a "selected candidate" compound to be a particular focus of development, going forward. (See Minutes of 5/28/99 Mtg. (Ex. 2099).) By that time, I, or those at my direction, had

synthesized the first salt form of R-fesoterodine, a hydrochloride salt, which is referred to in the Project records as "SPM 8228." (Id.)

14. At the Project Team meeting of 28 May 1999, it was noted that a stable and crystalline salt form of fesoterodine had been requested of my department, (id.), which is consistent with the necessity that the salt form of an active pharmaceutical ingredient exhibit the properties of purity, stability, and crystallinity in order for it to be viable oral pharmaceutical. At that time, I communicated to the Project Team that efforts to prepare a fesoterodine salt having those properties had been unsuccessful, resulting in oily masses not useful as pharmaceuticals. Specifically, I communicated that the fesoterodine hydrochloride, SPM 8228, "is amorphous and hygroscopic. We shall look now for [approximately] 20 other salts to improve the physiochemical properties." (Id.) The handwriting which appears on the face of Ex. 2099 is mine.

15. In fact, following the May 1999 Project Team meeting, I, or those at my direction, would need to synthesize and evaluate not 20, but more than 70 fesoterodine salts, Ex. 2006 at 58, made with more than 40 different organic acids, inorganic acids, and metal complexes. (See "Information about SPM 8224 & SPM 8272" (Ex. 2100) at 1.)

16. Of the over 70 fesoterodine salts that were prepared at my direction and observed over months as each was suspended in its solvent system, all but one yielded salts that were oils, not useful as oral pharmaceutical

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