

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES
LIMITED,
Petitioner,

v.

UCB PHARMA GMBH,
Patent Owner.

Case IPR2016-00510
Patent 6,858,650 B1

PATENT OWNER PRELIMINARY RESPONSE

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Ex. 2002	Declaration of William R. Roush, Ph.D.
Ex. 2003	C.V. for William R. Roush, Ph.D.
Ex. 2004	“Nilvebrant 1997 II” – Life Sciences (1997), 60(13/14), 1129-1136 – “Tolterodine – A New Bladder Selective Muscarinic Receptor Antagonist: Preclinical Pharmacological and Clinical Data”; L. Nilvebrant, B. Hallen, G. Larsson
Ex. 2005	“Callegari 2011” – British Journal of Clinical Pharmacology (2011), 72(2), 235-246 – “A comprehensive non-clinical evaluation of the CNS penetration potential of antimuscarinic agents for the treatment of overactive bladder”; E. Callegari, B. Malhotra, P. Bungay, R. Webster, K. Fenner, S. Kempshall, J. LaPerle, M. Michel, G. Kay
Ex. 2006	Trial Transcripts, <i>Pfizer Inc., et al. v. Sandoz Inc., et al.</i> , No. 1:13-cv-01110-GMS (D. Del. July 13-16, 2015)
Ex. 2007	File History for U.S.P.N. 7,384,980
Ex. 2008	“Wein 1994” – Urodynamics: Principles, Practice and Application (1994), 43-70 – “Pharmacologic treatment of voiding dysfunction”; A.J. Wein, P.A. Longurst, R.M. Levin
Ex. 2009	Detrol® LA Label (2004)
Ex. 2010	File History for U.S.P.N. 6,713,464
Ex. 2011	File History for U.S.P.N. 7,230,030
Ex. 2012	File History for U.S.P.N. 6,858,650

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- Ex. 2013 “Krise” – J. Med. Chem (1999), 42, 3094-3100 – “Novel Prodrug Approach for Tertiary Amines: Synthesis and Preliminary Evaluation of N-Phosphonooxymethyl Prodrugs”; J.P. Krise, J. Zygmunt, G.I. Georg, V.J. Stella
- Ex. 2014 “Sinkula” – Journal of Pharmaceutical Sciences (1975), 64(2), 181-210 – “Rationale for Design of Biologically Reversible Drug Derivatives: Prodrugs”; A.A. Sinkula, S.H. Yalkowski
- Ex. 2015 “Bundgaard (1991)” – Drugs of the Future (1991), 16(5), 443-458 – “Novel Chemical Approaches in Prodrug Design”; H. Bundgaard
- Ex. 2016 “Jann” – Clinical Pharmacokinetics (1985), 10, 315-333 – “Clinical Pharmacokinetics of the Depot Antipsychotics”; M.J. Jann, L. Ereshefsky, S.R. Saklad
- Ex. 2017 “Beresford” – Drugs (1987), 33, 31-49 – “Haloperidol Decanoate a Preliminary Review of Its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Use in Psychosis”; R. Beresford, A. Ward
- Ex. 2018 U.S.P.N. 7,384,980

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