

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 No. IPR2016-00510

Patent No. 6,858,650

**PATENT OWNER'S AMENDED LIST OF EXHIBITS PURSUANT TO 37
C.F.R. § 42.63(e)**

IPR2016-00510
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Exhibit No.	Description
2001	Memorandum Opinion, <i>Pfizer Inc. et al. v. Sandoz, Inc. et al</i> , 13-cv-01110 (D. Del.).
2002	Declaration of William R. Roush.
2003	C.V. of William R. Roush.
2004	Lisbeth Nilvebrant et al., <i>Tolterodine – A New Bladder Selective Muscarinic Receptor Antagonist: Preclinical Pharmacological and Clinical Data</i> , 60 <i>Life Sciences</i> 1129 (1997) (“Nilvebrant 1997 II”).
2005	<i>British Journal of Clinical Pharmacology</i> (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 (“Callegari 2011”).
2006	Trial Transcript, July 13-16, 2015, <i>Pfizer Inc. et al. v. Sandoz, Inc. et al</i> , 13-cv-01110 (D. Del.).
2007	The file history of United States Patent No. 7,384,980.
2008	<i>Urodynamics: Principles, Practice and Application</i> (1994), 43-70 – “Pharmacologic treatment of voiding dysfunction”; A.J. Wein, P.A. Longurst, R.M. Levin. (“Wein 1994”).
2009	Detrol® LA Label 2004.
2010	File History for U.S.P.N. 6,713,464.
2011	File History for U.S.P.N. 7,230,030.
2012	File History for U.S.P.N. 6,858,650.
2013	Jeffrey P. Krise et al., <i>Novel Prodrug Approach for Tertiary Amines: Synthesis and Preliminary Evaluation of N-Phosphonooxymethyl Prodrugs</i> , 42 <i>J. Med. Chem.</i> 3094 (1999) (“Krise”).
2014	A.A. Sinkula et al., <i>Rationale for Design of Biologically Reversible Drug Derivatives: Prodrugs</i> , 64 <i>J. Pharm. Sci.</i> 181 (1975) (“Sinkula”).
2015	Hans Bundgaard, <i>Novel Chemical Approaches in Prodrug Design</i> , 16 <i>Drugs of the Future</i> 443 (1991) (“Bundgaard (1991)”).
2016	Michael W. Jann et al., <i>Clinical Pharmacokinetics of the Depot Antipsychotics</i> , 10 <i>Clinical Pharmacokinetics</i> 315 (1985) (“Jann”).
2017	R. Beresford et al., <i>Haloperidol Decanoate a Preliminary Review of Its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Use in Psychosis</i> , 22 <i>Drugs</i> 31 (1987) (“Beresford”).
2018	United States Patent No. 7,384,980.

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2019	United States Patent No. 6,858,650.
2020	Transcript of the Deposition of Steven Patterson, Ph.D., dated October 4, 2016, Case IPR2016-00510, Case IPR2016-00512, Case IPR2016-00514, Case IPR2016-00516, Case IPR2016-00517 (“Patterson Tr.”).
2021	Declaration of Hans Maag, Sc.D.
2022	Declaration of William R. Roush, Ph.D.
2023	Declaration of Scott A. MacDiramid, M.D., FRCPSC.
2024	Declaration of Leonard J. Chyall, Ph.D.
2025	Declaration of Claus O Meese, Ph.D.
2026	Transcript of the Deposition of Culley C. Carson III, M.D., dated August 25, 2016, C.A. No. 15-cv-0079 (D. Del.).
2026A	Excerpts of Transcript of the Deposition of Culley C. Carson III, M.D., dated August 25, 2016, C.A. No. 15-cv-0079 (D. Del.). ¹
2027	Transcript of the Deposition of David R. Janero, Ph.D., dated August 16, 2016, C.A. No. 15-cv-0079 (D. Del.).
2027A	Excerpts of Transcript of the Deposition of David R. Janero, Ph.D., dated August 16, 2016, C.A. No. 15-cv-0079 (D. Del.). ²
2028	Jiunn H. Lin & Anthony Y.H. Lu, <i>Role of Pharmacokinetics and Metabolism in Drug Discovery and Development</i> , 49 <i>Pharmacological Reviews</i> 407 (1997) (“Lin & Lu”).
2029	N. Brynne et al., <i>Fluoxetine Inhibits the Metabolism of Tolterodine – Pharmacokinetic Implications and Proposed Clinical Relevance</i> 48 <i>BR. J. CLIN. PHARMACOL.</i> 553-63 (“Brynne 1999”).
2030	C.V. of Hans Maag, Ph.D.
2031	Alan J. Wein, <i>Pharmacologic Options for the Overactive Bladder</i> , 51 <i>Urology (SUPP. 2A)</i> 43 (1998) (“Wein 1998”).
2032	Lisbeth Nilvebrant et al., <i>Tolterodine – A New Bladder-Selective Antimuscarinic Agent</i> , 327 <i>Eur. J. Pharmacol.</i> 196 (1997) (“Nilvebrant 1997 III”).
2033	J. Andrew Fantl et al., <i>Urinary Incontinence in Adults: Acute and Chronic Management</i> , in <i>Clinical Practice Guideline 1996 Update</i> (U.S. Dep’t of Health & Human Servs., AHCPR Publication No. 96-0682, 1996) (“AHCPR”).

¹ Served but not filed, as supplemental evidence, pursuant to 37 C.F.R. § 42.64(b)(2).

² Served but not filed, as supplemental evidence, pursuant to 37 C.F.R. § 42.64(b)(2).

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2034	H. Madersbacher et al., <i>Trospium Chloride Versus Oxybutynin: A Randomized, Double-Blind, Multicentre Trial in the Treatment of Detrusor Hyper-Reflexia</i> , 75 Br. J. Urol. 452 (1995).
2035	G. Schladitz-Keil et al., <i>Determination of the Bioavailability of the Quaternary Ammonium Compound Trospium Chloride in Man from Urinary Excretion Data</i> , 36 Arzneimittel Forschung/Drug Res. 984 (1986).
2036	Ditropan XL® Prescribing Information, Revised 07/2013.
2037	R.J. Baigre et al., <i>Oxybutynin: Is It Safe?</i> , 62 Brit. J. Urol. 319 (1988).
2038	H. Madersbacher et al., <i>A Urodynamically Controlled Multicenter Study in Patients with Urge Incontinence: Tolerability and Efficacy of Propiverine Hydrochloride in Comparison to Oxybutynin</i> , in International Continence Society, 27th Annual Meeting, Yokohama, Abst. 187 (Sept. 1993) (“Madersbacher”).
2039	Hiroyuki Miyachi et al., <i>Novel Imidazole Derivatives with Subtype-Selective Antimuscarinic Activity (1)</i> , 8 Bioorg. Med. Chem. Lett. 2163 (1998) (“Miyachi”).
2040	Lisbeth Nilvebrant, <i>Clinical Experiences with Tolterodine</i> , 68 Life. Sci. 2549 (2001) (“Nilvebrant 2001”).
2041	Carolyn M. Smith & Rob M. Wallis, <i>Characterization of [³H]-Darifenacin as a Novel Radioligand for the Study of Muscarinic M₃ Receptors</i> , 17 J. Recept. Signal Tr. R. 177 (1997).
2042	Karl-Erik Andersson, <i>The Overactive Bladder: Pharmacologic Basis of Drug Treatment</i> , 50 Urology (SUPP. 6A) 44 (1997) (“Andersson 1997”).
2043	Taniguchi et al., <i>Agents for the Treatment of Overactive Detrusor. IX. Synthesis and Pharmacological Properties of Metabolites of N-tert-Butyl-4,4-diphenyl-2-cyclopentylamine (FK584) in Human Urine</i> , 44 CHEM. PHARM. BULL. 1188, (1996).
2044	Yasuo Sasaki et al., <i>Effect of NS-21, an Anticholinergic Drug with Calcium Antagonistic Activity, on Lower Urinary Tract Function in a Rat Model of Urinary Frequency</i> , 4 Int. J. Urol. 401 (1997) (“Sasaki (1997)”).
2045	Hiroaki Kikukawa, <i>Pharmacologic Actions of Temiverine (p-INN) and its Active Metabolite, RCC-36, on Isolated Human Urinary Bladder Muscle</i> , 5 Int. J. Urol. 268 (1998).
2046	N. Mealy & J. Castañer, <i>YM-905</i> , 24 Drugs Future 871 (1999) (“Mealy & Castañer”).

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2047	L.P. Balant et al., <i>Prodrugs for the Improvement of Drug Absorption via Different Routes of Administration</i> , 15 <i>European J. Drug Metabolism & Pharmacokinetics</i> 143 (1990) (“Balant”).
2048	Kevin Beaumont et al., <i>Design of Ester Prodrugs to Enhance Oral Absorption of Poorly Permeable Compounds: Challenges to the Discovery Scientist</i> , 4 <i>Curr. Drug. Metab.</i> 461 (2003) (“Beaumont”).
2049	Valentino J. Stella et al., <i>Prodrugs and Site-Specific Drug Delivery</i> , 23 <i>J. Medicinal Chemistry</i> 1275 (1980) (“Stella”).
2050	Peter Ettmayer et al., <i>Lessons Learned from Marketed and Investigational Prodrugs</i> , 47 <i>J. Med. Chem.</i> 2393 (2004) (“Ettmayer”).
2051	Bruce D. Roth et al., <i>Relationship Between Tissue Selectivity and Lipophilicity for Inhibitors of HMG-CoA Reductase</i> , 34 <i>J. Med. Chem.</i> 463 (1991) (“Roth”).
2052	J. Magyar et al., <i>Effects of Norfluoxetine on the Action Potential and Transmembrane Ion Currents in Canine Ventricular Cardiomyocytes</i> , 370 <i>Naunyn Schmiedebergs Arch. Pharmacol.</i> 203 (2004) (“Magyar”).
2053	United States Patent No. 5,382,600 (the “600 patent”).
2054	Prescribing Information for Accupril® retrieved on March 10, 2015.
2055	Milind M. Narurkar et al., <i>Synthesis, Physicochemical Properties, and Cytotoxicity of a Series of 5'-Ester Prodrugs of 5-Iodo-2'-Deoxyuridine</i> , 5 <i>Pharm. Res.</i> 734, 734 (1988) (“Narurkar”).
2056	Thomas Hartung, <i>Food for Thought Look Back in Anger – What Clinical Studies Tell Us About Preclinical Work</i> , 30 <i>Altex</i> 275 (2013) (“Hartung”).
2057	Chart of FDA Approvals of New Drug Applications for New Molecular Entities and New Active Ingredients from January 1994 – December 1998.
2058	Daniel S. Sitar, <i>Clinical Pharmacokinetics of Bambuterol</i> , 31 <i>Clin. Pharmacokinet.</i> 246 (1996) (“Sitar”).
2059	J. Greg Slatter et al., <i>Bioactivation of the Anticancer Agent CPT- 11 to SN-38 by Human Hepatic Microsomal Carboxylesterases and the in vitro Assessment of Potential Drug Interactions</i> , 25 <i>Drug Metabolism & Disposition</i> 1157 (1997) (“Slatter”).
2060	C.V. of Scott A. MacDiramid, M.D., FRCPSC.
2061	Paul Abrams et al., <i>The Standardisation of Terminology of Lower Urinary Tract Function</i> , <i>Neurourol. Uro.</i> 21:167–78 (2002).
2062	Abrams P, Cardozo L, Khoury S, Wein A (eds), <i>Incontinence</i> , 5th International Consultation on Incontinence (5th Ed. 2013).

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