

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED,
ALEMBIC PHARMACEUTICALS LIMITED, TORRENT
PHARMACEUTICALS LIMITED, AND AMERIGEN PHARMACEUTICALS
LIMITED
Petitioners,

v.

UCB PHARMA GMBH
Patent Owner.

Patent No. 6,858,650
Case IPR2016-00510

**PETITIONER MYLAN PHARMACEUTICALS INC.'S AMENDED
LIST OF EXHIBITS PURSUANT TO 37 C.F.R. § 42.63(e)**

LIST OF EXHIBITS

- Ex. 1001: U.S.P.N. 6,858,650
- Ex. 1002: File History for U.S.P.N. 6,858,650
- Ex. 1003: Declaration of Dr. Steven Patterson, Ph.D.
- Ex. 1004: C.V. for Dr. Steven Patterson, Ph.D
- Ex. 1005: “Johansson” – WO 94/11337 Filed 6 November 1992 – “Novel 3,3-Diphenylpropylamines, Their Use and Preparation”
- Ex. 1006: “Andersson Review” – BJU International (1999), 84, 923-947 – “The Pharmacological Treatment of Urinary Incontinence”; K-E Andersson, R. Appell, L.D. Cardozo, C. Chapple, H.P. Drutz, A.E. Finkbeiner, F. Haab, and R. Vela Navarrete
- Ex. 1007: “Brynne 1997” – International Journal of Clinical Pharmacology and Therapeutics (1997), 35, 287-295 – “Pharmacokinetics and pharmacodynamics of tolterodine in man: a new drug for the treatment of urinary bladder overactivity”; N. Brynne, M.M.S. Stahl, B. Hallen, P.O. Edlund, L. Palmer, P. Hoglund, and J. Gabrielsson
- Ex. 1008: “Thomas” – British Heart Journal (1995), 74, 53-56 – “Concentration dependent cardiotoxicity of terodine in patients treated for urinary incontinence”; S. Thomas, P. Higham, K Hartigan-Go, F. Kamali, P. Wood, R. Campbell, and G. Ford
- Ex. 1009: “Detrol® Label” – Pharmacia & Upjohn
- Ex. 1010: “Postlind” – Drug Metabolism and Disposition (1998), 26 (4), 289-293 – “Tolterodine, A New Muscarinic Receptor Antagonist, Is Metabolized by Cytochromes P450 2D6 and 3A in Human Liver Microsomes”; H. Postlind, A. Danielson, A.

Lindgren, and S. Andersson

- Ex. 1011: “Brynne 1998” – Clinical Pharmacology & Therapeutics (May 1998), 63(5), 529-539 – “Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine”; N. Brynne, P. Dalen, G. Alvan, L. Bertilsson, and J. Gabrielsson
- Ex. 1012: “Bundgaard” – Elsevier 1985 – “Design of Prodrugs”
- Ex. 1013: “Berge 1977” – Journal of Pharmaceutical Sciences (1977), 66 (1), 1-19 – “Pharmaceutical Salts”; S. Berge, L., Bighley, and D. Monkhouse
- Ex. 1014: “Andersson 1998” – Drug Metabolism and Disposition (1998), 26(6), 528-535 – “Biotransformation of tolterodine, a new muscarinic receptor antagonist, in mice, rats, and dogs”; S. Andersson, A. Lindgren, and H. Postlind
- Ex. 1015: “Nilvebrant” – Pharmacology and Toxicology (1997), 81, 169-172 – “Antimuscarinic Potency and Bladder Selectivity of PNU-200577, a Major Metabolite of Tolterodine”; L. Nilvebrant, P. Gillberg, and B. Sparf
- Ex. 1016: “DeMaagd” – P&T (2012), 37(6), 345-361 – “Management of Urinary Incontinence”; G. DeMaagd and T. Davenport
- Ex. 1017: “Appell” – Urology (1997), 50, 90-96 – “Clinical efficacy and safety of tolterodine in the treatment of overactive bladder: a pooled analysis”; R. Appell
- Ex. 1018: “Ashworth” – Home Care Provider (1997), 2(3), 117-120 – “Is My Antihistamine Safe?”; L. Ashworth
- Ex. 1019: “Lipinski” – Advanced Drug Delivery Reviews, 1997
- Ex. 1020: “Bundgaard PCT” – WO 92/08459 Filed 11 November 1991 –

- “Topical Compositions for Transdermal Delivery of Prodrug Derivatives of Morphine”
- Ex. 1021: “AUA Guideline” – American Urological Association Education and Research (2014) – “Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline”; E. Gormley, et al
- Ex. 1022: “Pfizer 2012 Press Release” – Aug. 2, 2012 “Study Shows Toviaz is Effective in Reducing Urge Urinary Incontinence in Patients with Overactive Bladder After Suboptimal Response to Detrol LA” – www.pfizer.com
- Ex. 1023: “PM360” – April 1, 2012 “Overactive Bladder Market: Managing the Future” – [www. pm360online.com](http://www.pm360online.com)
- Ex. 1024: “Toviaz® Label” – Pfizer Labs
- Ex. 1025: “FDA Approval Letter” –NDA20-771
- Ex. 1026: “FDA Guidance” – Applications Covered by Section 505(b)(2) – October 1999 – FDA (CDER)
- Ex. 1027: “Gould” – International Journal of Pharmaceutics (1986), 3, 201-217 – “Salt Section for Basic Drugs”; P. Gould
- Ex. 1028: “Alabaster” – Discovery & Development of Selective M3 Antagonists for Clinical Use, 60 Life Science 1053 (1997)
- Ex. 1029: “Takeuchi” – 1,2,3,4-Tetrahydro-2-Isoquinolinecarboxylate Derivatives: A Novel Class of Selective Muscarinic Antagonists, III, in 213th ACS National Meeting, San Francisco, Abst. 046 (Apr. 13-17, 1997)
- Ex. 1030: “Goldberg” – DuP 532, an angiotensin II receptor antagonist: First administration and comparison with losartan, Clinical

- Pharmacology & Therapeutics, January 1997
- Ex. 1031: “Begley” – The Blood-brain Barrier: Principles for Targeting Peptides and Drugs to the Central Nervous System, *J. Phar. Pharmacol.* 1996, 48:136-146
- Ex. 1032: Dkt 6 2015-01-28 Summons Returned Executed, Case No. 1:15-cv-00079-GMS, *Pfizer, et al v Mylan Pharmaceutical Inc.* (Dist. of DE)
- Ex. 1033: Declaration of DeForest McDuff, Ph.D.
- Ex. 1034: CV for DeForest McDuff, Ph.D.
- Ex. 1035: Toviaz: Don’t Let Overactive Bladder Stop You In Your Tracks
- Ex. 1036: Toviaz U.S. and Worldwide Sales
- Ex. 1037: U.S. OAB Prescriptions and Shares by Drug (2008–2014)
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