

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

UCB PHARMA GMBH

Patent Owner

Case IPR2016-00510

Patent No. 6,858,650

**PETITIONER MYLAN PHARMACEUTICALS INC.'S REPLY TO
PATENT OWNER'S RESPONSE TO PETITION**

US2008 12345620 3

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- 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

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- 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

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