

IPR2017-00011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

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Case IPR2017-00011  
US Patent No. RE41,148

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**PATENT OWNER PRELIMINARY RESPONSE**

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**LIST OF EXHIBITS**

<b>Exhibit</b>	<b>Description</b>
2001	DECLARATION OF BERNHARDT L. TROUT, Ph.D.
2002	Curriculum Vitae of Bernhardt L. Trout, Ph.D.
2003	FDA Orange Book Listing for Shire's Adderall XR®
2004	FDA Approved Product Label for Shire's Adderall XR®
2005	Excerpts from File History of Burnside, U.S. Patent No. 6,322,819
2006	Excerpts from File History of Burnside, U.S. Patent No. RE42,096
2007	Excerpts from File History of Burnside, U.S. Patent No. 6,605,300
2008	Barr's Para IV Letter, IDS No. 1 (March 15, 2005), Exhibit 26 in File History of Burnside, US Patent No. RE 41,148
2009	Excerpts from Chambliss Expert Report, IDS No. 2 (Nov. 23, 2005), in File History of Burnside, US Patent No. RE 41,148
2010	Excerpts from Klibanov Expert Report, IDS No. 2 (April 25, 2005), in File History of Burnside, US Patent No. RE 41,148
2011	William E. Pelham, Jr. et al., Sustained Release and Standard Methylphenidate Effects on Cognitive and Social Behavior in Children with Attention Deficit Disorder, 80 Pediatrics 491 (1987)
2012	James M. Swanson et al., Letter, More Frequent Diagnosis of Attention Deficit-Hyperactivity Disorder, 333 New England J. of Med. 944 (1995)
2013	Paul J. Ambrosini et al., A Community Assessment, Open-Label Study of the Safety, Tolerability, and Effectiveness of Mixed Amphetamine Salts Extended Release in School-Age Children With ADHD, 22 Current Med. Res. & Opinion 427 (2006)
2014	Joseph Biederman et al., A Randomized, Double-Blind, Placebo-Controlled, Parallel- Group Study of SLI381 (Adderall XR) in Children With Attention-Deficit/Hyperactivity Disorder, 110 Pediatrics 258 (2002)

- 2015 J.M. Swanson et al., The Use of Laboratory School Protocol to Evaluate Concepts About Efficacy and Side Effects of New Formulations of Stimulant Medications, 6 J. Attention Disorders S-73 (2002)
- 2016 William E. Pelham, Jr. et al., Pemoline Effects on Children with ADHD: A Time-Response by Dose-Response Analysis on Classroom Measures, 34 J. Am. Acad. Child & Adolescent Psychiatry 1504 (1995)
- 2017 Excerpts from File History of Burnside, US RE 41,148
- 2018 Kennerly S. Patrick & John S. Markowitz, Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder, 12 Human Psychopharmacology 527 (1997)
- 2019 Richard H. Weisler, Safety, Efficacy and Extended Duration of Action of Mixed Amphetamine Salts Extended-Release Capsules for the Treatment of ADHD, 6 Expert Opin. Op. in Pharmacotherapy 1003 (2005)
- 2020 FDA Approved Product Label for Shire's Adderall®
- 2021 Thomas Spencer et al., Efficacy of a Mixed Amphetamine Salts Compound in Adults with Attention-Deficit/Hyperactivity Disorder, 58 Arch. Gen. Psych. 775 (2001)
- 2022 James J. McGough et al., Pharmacokinetics of SLI381 (ADDERALL XR), an Extended-Release Formulation of Adderall, 42 J. Am. Acad. Child Adolesc. Psychiatry 684 (2003)
- 2023 Steven R. Pliszka, The Use of Psychostimulants in the Pediatric Patient, 45 Pediatric Clinics of North America 1085 (1998)
- 2024 SUPAC-MR: Modified Release Solid Oral Dosage Forms (Sept. 1997) ("1997 FDA Guidance")
- 2025 Institution Decision, IPR2016-01033
- 2026 *Shire v. Abhai*, Claim Construction Decision, DI 85
- 2027 Burnside, US RE 42096
- 2028 Food Effect Bioavail and Fed Bioequiv Studies (2002)

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