# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

V.

SHIRE LLC,

Patent Owner.

Case IPR2017-00011 US Patent No. RE41,148

PATENT OWNER PRELIMINARY RESPONSE



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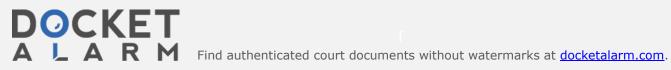
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	c) The formulation, when containing a total dose of 20mg, has an AU of about 467 to about 714ng·hr/ml	
	d) There was no reasonable expectation of success; the references are not enabling	



## IPR2017-00011

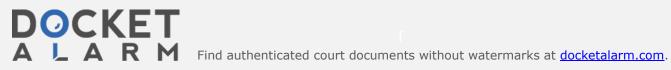
# Patent Owner's Preliminary Response

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### LIST OF EXHIBITS

Exhibit	Description
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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