

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN TECHNOLOGIES, INC.,
Petitioner

v.

MONOSOL RX, LLC,
Patent Owner

Case: IPR2017-00200

Patent 8,603,514

PATENT OWNER MONOSOL RX, LLC'S UPDATED EXHIBIT LIST

PATENT OWNER'S EXHIBIT LIST

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
*2001	Trial Transcript, <i>Reckitt Benckiser Pharms Inc. v. Watson Laboratories, Inc. et al.</i> , CA No. 14-1574-RGA (Nov. 3-4, 2015) (“Trial Tr.”)
*2002	<i>Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc. et al.</i> , Civil Case No. 1:13-1674, slip opinion (D. Del. June 3, 2016) (Richard G. Andrews, J.) (<i>Reckitt v. Watson</i>)
*2003	J. O. Morales and J. T. McConville, Manufacture and Characterization of Mucoadhesive Buccal Films, <i>European Journal of Pharmaceutics and v Biopharmaceutics</i> 77, pp. 187-99 (2011)
*2004	A. F. Borges et al., Oral Films: Current Status and Future Perspectives II – Intellectual Property, Technologies and Market Needs, <i>Journal of Controlled Release</i> 206, pp. 108–21
*2005	V.A. Perumal et al., Investigating a New Approach to Film Casting for Enhanced Drug Content Uniformity in Polymeric Films, <i>Drug Dev. & Indust. Pharm.</i> 34, pp. 1036-47 (2008)
*2006	H. Kathpalia and A. Gupte, An Introduction to Fast Dissolving Oral Thin Film Drug Delivery Systems: A Review, <i>Drug Delivery & Formulation</i> 10, pp. 667-84 (2013)
*2007	Declaration of Dr. Robert Langer
*2008	Deposition Transcript of Dr. Graham Buckton
*2009	V. A. Perumal, “Multipolymeric Monolayered Mucoadhesive Films for Drug Therapy,” Master’s Thesis (2007)
*2010	Morales et al., “The Influence of Recrystallized Caffeine on Water-Swellable Polymethacrylate Mucoadhesive Bucca Films,” <i>AAPS PharmSciTech</i> , Vol. 14, No. 2, 475–484 (2013)
*2011	U.S. Provisional App. Ser. No. 60/443,741

*2012	Curriculum Vitae of Dr. Robert Langer
*2013	C.A. No. 1:14-cv-01451-RGA, Trial Tr.
*2014	Lachman, L. et al., The Theory and Practice of Industrial Pharmacy (3d ed. 1986)
*2015	S. Puttipipatkachorn et al., "Drug physical state and drugpolymer interaction on drug release from chitosan matrix films" (2001)
*2016	J. Siepmann and N. Peppas entitled "Modeling of drug release from delivery systems based on hydroxypropyl methylcellulose" (2001)
*2017	Compos-Aldrete et al., "Influence of the viscosity grade and the particle size of HPMC on metronidazole release from matrix tablets", European Journal of Pharmaceutics and Biopharmaceutics, 43:173–178 (1997)
*2018	James E. De Muth, Basic Statistics and Pharmaceutical Statistical Applications (2d ed. 2006)
*2019	Staniforth, J.N., "Particle size analysis," Pharmaceutics – The Science of Dosage Form Design (Aulton ed.), Ch. 33 at p. 578 (1988)
*2020	P. Perugini et al., "Periodontal delivery of ipriflavone: new chitosan/PLGA film delivery system for a lipophilic drug," Int'l J. of Pharmaceutics, 252:1–9 (2003)
*2021	J. Yoo et al., "The physicodynamic properties of mucoadhesive polymeric films developed as female controlled drug delivery system," Int'l J. of Pharmaceutics, 309:139–145 (2006)
*2022	A. Dhanikula et al., "Development and Characterization of Biodegradable Chitosan Films for Local Delivery of Paclitaxel," The AAPS Journal, 6(3):1–12 (2004)
*2023	A. Ahmed et al., "Penciclovir solubility in Eudragit films: a comparison of X-ray, thermal, microscopic and release rate techniques," J. Pharm. & Biomedical Analysis, 34:945–956 (2004)
*2024	C. Amnuakit et al., "Skin permeation of propranolol from polymeric film containing terpene enhancers for transdermal use," Int'l J. of Pharmaceutics, 289:167–178 (2005)
*2025	U.S. Patent No. 7,425,292 to Yang et al.
*2026	Sigma-Aldrich Product Information Sheet re Caffeine (Anhydrous)

*2027	Shakeel et al., “Thermodynamics-based mathematical model for solubility prediction of glibenclamide in ethanol–water mixtures,” <i>Pharm. Dev. Technol.</i> , 2014; 19(6): 702–707
*2028	USP 905 (2002)
*2029	Donald J. Wheeler, <i>Advanced Topics in Statistical Process Control</i> (1st ed. 1995)
*2030	James E. De Muth, <i>Basic Statistics and Pharmaceutical Statistical Applications</i> (1st ed. 1999)
*2031	David S. Jones, <i>Pharmaceutical Statistics</i> (2002)
2032	Transcript of Patent Trial and Appeal Board Hearing on October 4, 2017

*Patent Owner’s exhibits 2001-2031 were previously filed and are listed here again pursuant to 37 C.F.R. § 42.63.

Respectfully submitted,

Date: October 10, 2017

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I hereby certify that on this 10th day of October 2017, the foregoing PATENT OWNER MONOSOL RX, LLC'S UPDATED EXHIBIT LIST were served by filing this document through the Patent Trial Appeal Board End To End system as well as by delivering a copy via electronic mail, by agreement of the parties, on the following counsel of record for Petitioner.

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