UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner

v.

HOSPIRA, INC.,
Patent Owner

Inter Partes Review No. IPR2016-01578
Patent 8,338,470

DECLARATION OF DR. ROBERT LINHARDT

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LIST OF EXHIBITS	
Exhibit	**Document**
1007	2010 Precedex® Label ("the 2010 Label").
1013	FDA Memorandum by Cynthia G. McCormick, M.D., dated November 30, 1999. ("the McCormick FDA Memorandum").
1015	Giorgi et al., International Journal for Quality in Health Care, Vol. 22, No. 3, 170-178 (2010) ("Giorgi").
1016	Eichhorn, The Official Journal of the Anesthesia Patient Safety Foundation, Spring 2010 ("Eichhorn").
1017	Palmgren, European Journal of Pharmaceutics and Biopharmaceutics, June 29, 2006 ("Palmgren").
1018	Lavoisier Documents; Lavoisier Sodium Chloride Product Sheet, June 2009 ("Lavoisier").
1019	FDA Memorandum by Bob A. Rappaport, M.D., dated November 5, 1999. ("the Rappaport FDA Memorandum").
1025	Packaging Drugs and Pharmaceuticals, Wilmer A. Jenkins and Kenton R. Osborn, 1993.
1026	"Pharmaceutical dosage forms, parenteral medications" edited by Kenneth E. Avis, et al. 2nd Edition, p. 161, 1992.
1027	"Sterile Pharmaceutical Packaging: Compatibility and Stability" Y. John Wang and Yie W. Chien, p. 16, 1984.
1028	Paula Youngberg Webb, et al. "The Keys to RTU Parenterals," Pharmaceutical Formulation & Quality, Vol. 11, No. 5, p. 40, September 2009.
1044	"Injectable medicines," WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, http://whocc.goeg.at/Glossary/PreferredTerms.

1057	Declaration of Huailiang Wu, U.S. Application No. 13/541,524 ("the Wu Declaration").
2001	U.S. Patent No. 8,242,158 ("the '158 Patent").
2002	U.S. Patent No. 8,338,470 ("the '470 Patent").
2003	U.S. Patent No. 8,455,527 ("the '527 Patent").
2004	U.S. Patent No. 8,648,106 ("the '106 Patent").
2008	"Guidance for Industry: Drug Stability Guidelines," FDA Center for Veterinary Medicine, p. 26, Dec. 2008.
2009	"Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products," FDA Center for Drug Evaluation and Research, p. 10, Nov. 2003.
2011	Speaker, T.J. et al., "A Study of the Interaction of Selected Drugs and Plastic Syringes," PDA J Pharm Sci and Tech, 45:212-217 (1991).
2012	Kaur, M. et al., "Current role of dexmedetomidine in clinical anesthesia and intensive care," Anesth Essays Res. 2011 Jul-Dec., 5(2): 128-133.
2013	Ecoflac® Plus Brochure, B|Braun.
2014	P. Donyai and G. Sewell, "Physical and chemical stability of paclitaxel infusions in different container types," J. Oncol. Pharm. Practice, 12, pp. 211-222 (2006).
2015	Anes, J. et al., "Use of Plastics for Parenteral Packaging," Pharmaceutical Dosage Forms: Parenteral Medications Volume 1, 2d Ed. (1992).
2016	Webb, P. et al., "Ensure Safety, Efficacy of Ready-to-Use IV Drug Products," PFQ Vol. 11, No. 6, Oct./Nov. 2009.
2017	"Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics," FDA Center for Drug Evaluation and Research, pp. 7-10, May 1999.
2018	Dahlstrom, M. et al., "Impact of polymer surface affinity of novel antifouling agents," Biotechnol Bioeng. 2004 Apr 5;86(1):1-8.
2024	Label for 0.9% w/v Sodium Chloride Intravenous Infusion BP, B. Braun Melsungen AG, Dec. 2010, available at https://www.old.health.gov.il/units/pharmacy/trufot/alonim/Sodium_Chloride_0-9_DR_1319972870952.pdf.

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