

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. IPR2016-01580
Patent 8,648,106

DECLARATION OF DR. MICHAEL RAMSAY

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LIST OF EXHIBITS

Exhibit	Document
1002	Declaration of Dr. James Cain.
1006	U.S. Patent No. 6,716,867 (“the ’867 Patent”).
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”).
1028	Paula Youngberg Webb, et al. “The Keys to RTU Parenterals,” Pharmaceutical Formulation & Quality, Vol. 11, No. 5, p. 40, September 2009.
1029	“Parenteral Preparations”, Ch. 84, p. 1469, Remington’s Pharmaceutical Sciences 16th Edition (1980).
1039	G. DiSilvio, M. Jacoby, D. Weiner, A. Broussard, P. Callahan, and J. Cain, “Intranasal Dexmedetomidine & Midazolam: A Novel Sedation Technique for Infant PFT,” Society for Pediatric Anesthesia, Phoenix, Arizona (March 2015).
1044	“Injectable medicines,” WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies,

	http://whocc.goeg.at/Glossary/PreferredTerms .
1046	A. Desai and Mary Lee, "Gibaldi's Drug Delivery Systems," American Society of Health-System Pharmacists, Bethesda (2007).
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").
2010	C.E. Blogg, M.A.E. Ramsay, and J.D. Jarvis, "Infection Hazard from Syringes," Br. J. Anaesth., 46, pp. 260-262 (1974).
2016	Webb, P. et al., "Ensure Safety, Efficacy of Ready-to-Use IV Drug Products," PFQ Vol. 11, No. 6, Oct./Nov. 2009.
2022	Yuen et al., "A Comparison of Intranasal Dexmedetomidine and Oral Midazolam for Premedication in Pediatric Anesthesia: A Double-Blinded Randomized Controlled Trial," Anesthesia & Analgesia 106(6):1715-1721 (June 2008).
2023	"Centralized Intravenous Additive Services (CIVAS): The state of the art in 2010," Annales Pharmaceutiques Francaises (2011) 69:30-37.
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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