

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

PATENT OWNER PRELIMINARY RESPONSE

PURSUANT TO 37 C.F.R. § 42.107

LIST OF EXHIBITS

Exhibit	Description
1002	Declaration of Dr. James Cain.
1003	Declaration of Dr. Alpaslan Yaman.
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”).
1025	Packaging Drugs and Pharmaceuticals, Wilmer A. Jenkins and Kenton R. Osborn, p. 259, 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.
1033	Liu, U.S. 6,310,094.
1034	Linden, P., et al., Ready-to-use injection preparations versus conventional reconstituted admixtures: economic evaluation in a real-life setting, PharmacoEconomics, Vol. 20, No. 8, 529-536 (2002).
1035	Cain, TraumaCare, July 2007, p. 5.
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).
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	http://whocc.goeg.at/Glossary/PreferredTerms .
1049	Office Action Response, mailed Sept. 17, 2012, U.S. Application No. 13/541,524.
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”).
2005	Declaration of Dr. Robert Linhardt (“the Linhardt Declaration”).
2006	Declaration of Dr. Michael Ramsay (“the Ramsay Declaration”).
2007	Accelerated Examination Support Document, U.S. Patent Application Serial No. 13/541,524.
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.
2010	C.E. Blogg, M.A.E. Ramsay, and J.D. Jarvis, “Infection Hazard from Syringes,” Br. J. Anaesth., 46, pp. 260-262 (1974).
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.
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	chlorpromazine with a new multilayer material for infusion containers,” <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 37: 259–264(2005).
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2021	T. Casey, “Hospira Slices into Plastic Medical Waste with New IV Bags,” <i>Clean Technica</i> , Dec. 4, 2009, available at http://cleantechnica.com/2009/12/04/hospira-slices-into-plastic-medical-waste-with-new-iv-bags/ .
2022	Yuen et al., “A Comparison of Intranasal Dexmedetomidine and Oral Midazolam for Premedication in Pediatric Anesthesia: A Double-Blinded Randomized Controlled Trial,” <i>Anesthesia & Analgesia</i> 106(6):1715-1721 (June 2008).
2023	“Centralized Intravenous Additive Services (CIVAS): The state of the art in 2010,” <i>Annales Pharmaceutiques Francaises</i> (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 .
2025	Ketalar TM Label (ketamine hydrochloride injection), Mar. 2012, p. 4, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/016812s0391bl.pdf .
2026	Alkeran TM Label, June 2007, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020207s0171bl.pdf .
2027	Desmaris, R. et al., “Stability of Melphalan in 0.9% Sodium Chloride Solutions Prepared in Polyvinyl Chloride Bags for Intravenous Injection,” <i>Drugs R. D.</i> , 14(3): 253-259, Jul. 2015.

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