

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner,

v.

CEPHALON, INC.,
Patent Owner.

Case IPR2016-00111
Patent No. 8,895,756 B2

**CEPHALON, INC.'S PRELIMINARY PATENT OWNER RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

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<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	12, 13
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PATENT OWNER'S LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
2001	TREANDA® Prescribing Information
2002	“Treanda New Drug Application for the Treatment of Chronic Lymphocytic Leukemia Granted Priority Review Status by FDA,” <i>Drugs.com</i> (December 3, 2007)
2003	File History of U.S. Patent No. 8,609,863
2004	“FDA Approves Treanda,” <i>Drugs.com</i> (March 20, 2008)
2005	“Cephalon Receives FDA Approval for Treanda to Treat Patients with Relapsed Indolent Non-Hodgkin’s Lymphoma,” <i>Drugs.com</i> (October 31, 2008)
2006	Brad S. Kahl, et al., “Bendamustine Is Effective Therapy in Patients with Rituximab-Refractory, Indolent B-cell Non-Hodgkin Lymphoma: Results From a Multicenter Study,” <i>Cancer</i> 106 (January 1, 2010)
2007	K. Sue Robinson, et al., “Phase II Multicenter Study of Bendamustine Plus Rituximab in Patients with Relapsed Indolent B-Cell and Mantle Cell Non-Hodgkin’s Lymphoma,” 26 <i>J. Clin. Oncol.</i> 4473 (September 20, 2008)
2008	Wolfgang U. Knauf, et al., “Phase III Randomized Study of Bendamustine Compared with Chlorambucil in Previously Untreated Patients with Chronic Lymphocytic Leukemia,” 27 <i>J. Clin. Oncol.</i> 4278 (September 10, 2009)
2009	Wolfgang U. Knauf, et al., “Bendamustine Compared with Chlorambucil in Previously Untreated Patients with Chronic Lymphocytic Leukaemia: Updated Results of a Randomized Phase III Trial,” 159 <i>Brit. J. Hematology</i> 67 (August 4, 2012)

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