

**UNITED STATES PATENT AND TRADEMARK OFFICE**

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

FRESENIUS KABI USA, LLC  
*Petitioner,*

v.

CEPHALON, INC.  
*Patent Owner.*

---

Case IPR2016-00098  
Patent No. 8,791,270 B2

---

**PATENT OWNER'S UPDATED EXHIBIT LIST**

**PATENT OWNER'S UPDATED EXHIBIT LIST**

<b>EXHIBIT</b>	<b>DESCRIPTION</b>
<b>2001</b>	TREANDA® Prescribing Information
<b>2002</b>	“Treanda New Drug Application for the Treatment of Chronic Lymphocytic Leukemia Granted Priority Review Status by FDA,” <i>Drugs.com</i> (December 3, 2007)
<b>2003</b>	Kanti R. Rai, et al., “Fludarabine Compared with Chlorambucil as Primary Therapy for Chronic Lymphocytic Leukemia,” 343(24) <i>New Eng. J. Med.</i> 1752 (December 14, 2000)
<b>2004</b>	M. J. Keating, et al., “Long-Term Follow-up of Patients with Chronic Lymphocytic Leukemia (CLL) Receiving Fludarabine Regimens as Initial Therapy,” 92 <i>Blood</i> 1165 (August 15, 1998)
<b>2005</b>	Guillaume Dighiero, et al., “Chlorambucil in Indolent Chronic Lymphocytic Leukemia,” 338 <i>New Eng. J. Med.</i> 1506 (May 21, 1998)
<b>2006</b>	The French Cooperative Group on Chronic Lymphocytic Leukemia, “Comparison of Fludarabine, Cyclophosphamide / Doxorubicin / Prednisone, and Cyclophosphamide / Doxorubicin / Vincristine / Prednisone in Advanced Forms of Chronic Lymphocytic Leukemia: Preliminary Results of a Controlled Clinical Trial,” 20 <i>Seminars in Oncology</i> 21 (October 1993)
<b>2007</b>	Suzanne Demko, et al., “FDA Drug Approval Summary: Alemtuzumab as Single-Agent Treatment for B-Cell Chronic Lymphocytic Leukemia,” 13 <i>The Oncologist</i> 167 (2008)
<b>2008</b>	A. J. Davies, et al., “Tositumomab and Iodine I 131 Tositumomab for Recurrent Indolent and Transformed B-Cell Non-Hodgkin's Lymphoma,” 22 <i>J. Clin. Oncol.</i> 1469 (April 15, 2004)

EXHIBIT	DESCRIPTION
2009	Samuel A. Jacobs, et al., "Phase II Trial of Short-Course CHOP-R Followed by <sup>90</sup> Y-ibritumomab Tiuxetan and Extended Rituximab in Previously Untreated Follicular Lymphoma," 14(21) <i>Clin. Cancer Res.</i> 7088 (November, 1, 2008)
2010	Richard I. Fisher, et al., "Comparison of a Standard Regimen (CHOP) with Three Intensive Chemotherapy Regimens for Advanced Non-Hodgkin's Lymphoma," 328(14) <i>New Eng. J. Med.</i> 1002 (April 8, 1993)
2011	Peter McLaughlin, et al., "Fludarabine, Mitoxantrone, and Dexamethasone: An Effective New Regimen for Indolent Lymphoma," 14 <i>J. Clin. Oncol.</i> 1262 (April 1996)
2012	File History of U.S. Patent No. 8,609,863
2013	"FDA Approves Treanda," <i>Drugs.com</i> (March 20, 2008)
2014	"Cephalon Receives FDA Approval for Treanda to Treat Patients with Relapsed Indolent Non-Hodgkin's Lymphoma," <i>Drugs.com</i> (October 31, 2008)
2015	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)
2016	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)
2017	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)

EXHIBIT	DESCRIPTION
2018	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)
2019	Norbert Niederle, et al., "Bendamustine Compared to Fludarabine as Second-Line Treatment in Chronic Lymphocytic Leukemia," 92 <i>Ann. Hematology</i> 653 (January 23, 2013)
2020	Teva Pharmaceutical Industries Limited, Form 20-F, 2014
2021	Teva Pharmaceutical Industries Limited, Form 20-F, 2011
2022	Cephalon, Inc., Form 10-K, 2010
2023	Cephalon, Inc., Form 10-K, 2009
2024	Cephalon, Inc., Form 10-K, 2008
2025	Alternate Copy of Birgit Maas et al., Stability of Bendamustine Hydrochloride in Infusions, 49 PHARMAZIE 775 (1994) produced in <i>Fresenius Kabi USA, LLC v. Cephalon, Inc.</i> , IPR2016-00111, Ex. 1009 (PTAB Nov. 2, 2015)
2026	Alternate Copy of Birgit Maas et al., Stability of Bendamustine Hydrochloride in Infusions, 49 PHARMAZIE 775 (1994) produced in, <i>Agila Specialties Inc. v. Cephalon, Inc.</i> , IPR2015-00503, Ex. 1010 (PTAB Dec. 24, 2014)
2027	Thissen Laboratories, Batch 02K27 Certificate of Analysis
2028	Thissen Laboratories, Batch 03C08 Certificate of Analysis
2029	Thissen Laboratories, Batch 03H08 Certificate of Analysis

IPR2016-00098 (Paper No. 19)  
Patent Owner's Updated Exhibit List

<b>EXHIBIT</b>	<b>DESCRIPTION</b>
<b>2030</b>	Thissen Laboratories, Batch 03H07 Certificate of Analysis
<b>2031</b>	Cephalon, Inc.'s Preliminary Patent Owner Response Pursuant to 37 C.F.R. § 42.107, IPR2016-00026, Paper 12 (PTAB Jan. 20, 2016)
<b>2032</b>	CONFIDENTIAL – Agreement between the Parties

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.