

Paper No. \_\_\_\_  
Filed: August 3, 2015

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS IV LLC  
Petitioner

v.

PHARMACYCLICS LLC  
Patent Owner

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Case IPR2015-01076  
U.S. Patent No. 8,754,090

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**PATENT OWNER'S MOTION FOR *PRO HAC VICE* ADMISSION OF  
LAUREN M. NOWIERSKI UNDER 37 C.F.R. § 42.10**

**PATENT OWNER'S UPDATED EXHIBIT LIST**

<b>Pharmacyclics Exhibit No.</b>	<b>DESCRIPTION</b>
2001	FDA Press Release, "FDA Approves Imbruvica For Rare Blood Cancer" (Nov. 13, 2013), <i>available at</i> <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374761.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374761.htm</a>
2002	Howard, O., "Mantle Cell Lymphoma." <i>Malignant Lymphomas</i> Ed. Grossbard, ML London: BC Decker Inc. 2002 135-51)
2003	Wang, M., et al., Targeting BTK with Ibrutinib in Relapsed or Refractory Mantle-Cell Lymphoma, 369 N. Eng. J. Med. 507 (2013)
2004	European Medicines Agency, "Assessment Report for Torisel" (August 25, 2009), <i>available at</i> <a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000799/WC500039918.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/000799/WC500039918.pdf</a>
2005	Ohio State University Medical Center. "Drug shows surprising efficacy as treatment for chronic leukemia, mantle cell lymphoma." ScienceDaily (June 19, 2013) <i>available at</i> <a href="http://www.sciencedaily.com/releases/2013/06/130619195217.htm">www.sciencedaily.com/releases/2013/06/130619195217.htm</a> .
2006	Johnson & Johnson Press Release, "Ibrutinib Receives Two Oncology Breakthrough Therapy Designations from U.S. Food and Drug Administration" (Feb. 12, 2013), <i>available at</i> <a href="http://www.jnj.com/news/all/ibrutinib-receives-two-oncology-breakthrough-therapy-designations-from-us-food-and-drug-administration">http://www.jnj.com/news/all/ibrutinib-receives-two-oncology-breakthrough-therapy-designations-from-us-food-and-drug-administration</a>
2007	S. 3187 Prescription Drug User Fee Amendments of 2012
2008	Office Action, Non-Final Rejection (March 13, 2013), U.S. Patent App. No. 13/340,522
2009	Notice of Allowability (March 31, 2014), U.S. Patent App. No. 13/340,522
2010	Chang, B.Y., et al "Egress of CD191CD51 cells into peripheral blood following treatment with the Bruton tyrosine kinase inhibitor ibrutinib in mantle cell lymphoma patients" <i>Blood</i> , 122(14): 2412-2424
2011	Schlette, E., et al, "CD23 Expression in Mantle Cell Lymphoma: Clinicopathologic Features of 18 Cases" <i>Am J. Clin. Pathol.</i> 2003;120:760-766

Pharmacyclics Exhibit No.	DESCRIPTION
2012	Form ADV Brochure of Hayman Capital Management L.P. (Mar. 30, 2015)
2013	Form ADV of Hayman Capital Management L.P. (Mar. 30, 2015)
2014	Delaware Certificates of Formation for Coalition for Affordable Drugs (ADROCA) LLC and Coalition for Affordable Drugs II LLC through XV
2015	Request for Continued Examination and Information Disclosure Statement (January 31, 2014), U.S. Patent App. No. 13/340,522
2016	Argyriou, A.A., et al., “Bortezomib–induced peripheral neurotoxicity: an update,” <i>Arch Toxicol</i> (2014) 88:1669–1679
2017	PRNewswire, “Pharmacyclics Reports Fourth Quarter and Full Year 2014 Financial Results and Provides Business Updates” (Feb. 18, 2015), available at <a href="http://www.prnewswire.com/news-releases/pharmacyclics-reports-fourth-quarter-and-full-year-2014-financial-results-and-provides-business-updates-300038067.html">http://www.prnewswire.com/news-releases/pharmacyclics-reports-fourth-quarter-and-full-year-2014-financial-results-and-provides-business-updates-300038067.html</a>
2018	Highlights of Prescribing Information: Imbruvica (ibrutinib), <i>available at</i> <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203147s000lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203147s000lbl.pdf</a>
2019	The Wall Street Journal, “New Hedge Fund Strategy: Dispute the Patent, Short the Stock;” (2015) <i>available at</i> <a href="http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408">http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408</a> .
2020	Law360, “Shire Drugs Are Next Targets of Hedge Fund’s AIA Reviews;” (2015), <i>available at</i> <a href="http://www.law360.com/articles/638836/shire-drugs-are-next-targets-of-hedge-fund-s-aia-reviews">http://www.law360.com/articles/638836/shire-drugs-are-next-targets-of-hedge-fund-s-aia-reviews</a> .
2021	Hayman Capital Management, L.P. “Statement of J. Kyle Bass Chief Investment Officer, Hayman Capital Management, L.P.,” (2015).
2022	Delaware Department of State: Division of Corporations, “Coalition for Affordable Drugs IV LLC – Entity Details”
2023	IP Watchdog, “Senator Coons – Patents Are about the American Dream;” (2015), <i>available at</i> <a href="http://www.ipwatchdog.com/2015/03/05/senator-coons-patents-">http://www.ipwatchdog.com/2015/03/05/senator-coons-patents-</a>

Pharmacyclics Exhibit No.	DESCRIPTION
	are-about-the-american-dream/id=55442/.
2024	Pharma: The Catalyst, “What They Are Saying: Close Patent Loopholes That Threaten Innovation for Patients;” (2015), available at <a href="http://catalyst.phrma.org/what-they-are-saying-close-patent-loopholes-that-threaten-innovation-for-patients">http://catalyst.phrma.org/what-they-are-saying-close-patent-loopholes-that-threaten-innovation-for-patients</a> .
2025	Affidavit of Lauren M. Nowierski

## **I. STATEMENT OF PRECISE RELIEF REQUESTED**

Pursuant to 37 C.F.R. § 42.10(c), Patent Owner Pharmacyclics LLC (“Pharmacyclics”) respectfully requests that the Patent Trial and Appeal Board (“Board”) admit Lauren M. Nowierski *pro hac vice* to act as back-up counsel for Pharmacyclics in this proceeding, IPR2015-01076.

## **II. STATEMENT OF REASONS FOR THE RELIEF REQUESTED**

### **a. GOVERNING LAW, RULES, AND PRECEDENT**

Pursuant to 37 C.F.R. § 42.10(c),

The Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions as the Board may impose. For example, where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.

The Board authorized the parties to file *pro hac vice* motions in its April 30, 2015 Notice of Filing Date Accorded to Petition, Paper No. 4, at 2. *Unified Patents, Inc. v. Parallel Iron, LLC*, Case IPR2013-00639, Paper No. 7 (“Order – Authorizing Motion For *Pro Hac Vice* Admission – 37 C.F.R. § 42.10”) (Oct. 15, 2013)

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