Paper No. _____ Filed: June 23, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC Petitioner,

v.

CELGENE CORPORATION Patent Owner

> Case IPR2015-01103 Patent 6,315,720

PATENT OWNER EXHIBIT LIST AS OF June 23, 2016 PURSUANT TO 37 C.F.R. § 42.63(e)

A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET

EXHIBIT NO.	DESCRIPTION
Exhibit 2001	Thalomid [®] June 2014 Package Insert
Exhibit 2002	Dr. V. Pannikar, WHO, "The Return of Thalidomide: New Uses and Renewed Concerns."
Exhibit 2003	Revlimid [®] February 2015 Package Insert
Exhibit 2004	Pomalyst [®] April 2015 Package Insert
Exhibit 2005	FDA website, "About the FDA;" (2014).
Exhibit 2006	Uhl, Kathleen, et al. "Thalidomide Use in the US, Experience with Pregnancy Testing in the S.T.E.P.S.® Programme;" (2006).
Exhibit 2007	Celgene Thalomid [®] NDA submission re: Enhanced S.T.E.P.S. [®]
Exhibit 2008	Thalomid [®] September 2001 Package Insert
Exhibit 2009	September 2001 Thalomid [®] Package Insert approval letter
Exhibit 2010	May 2006 Thalomid [®] FDA approval letter
Exhibit 2011	December 2005 Revlimid [®] FDA approval letter
Exhibit 2012	February 2013 Pomalyst [®] FDA approval letter
Exhibit 2013	Koren, G., et al "Drugs in Pregnancy;" (1998).
Exhibit 2014	Honigfeld, G., "Effects of the Clozapine National Registry System on Incidence of Death Related to Agranulocytosis;" (1996).
Exhibit 2015	Celgene January 2005 Form 8-K
Exhibit 2016	Kirn, T. "Mandatory FDA restrictions on the way for isotretinoin: voluntary programs deemed ineffective;" (2005).
Exhibit 2017	PR Newswire "Isotretinoin Makers Reach Agreement with Celgene on S.T.E.P.S.® Risk Management Patents"
Exhibit 2018	FDA Orphan Drug Designations and Approvals for Thalidomide
Exhibit 2019	FDA Orphan Drug Designations and Approvals for Lenalidomide
Exhibit 2020	FDA Orphan Drug Designations and Approvals for Pomalidomide
Exhibit 2021	Celgene December 2014 Form 10-K
Exhibit 2022	Center for Drug Evaluation and Research, FDA, "Transcript: 47 th Meeting of the Dermatologic and Ophthalmic Drugs Advisory

Case IPR2015-01103 Patent 6,315,720 Patent Owner's Exhibit List

EXHIBIT NO.	DESCRIPTION
	Committee;" (1997).
Exhibit 2023	FDA, "Transcript: Thalidomide: Potential Benefits and Risk Open Public Scientific Workshop;" (1997).
Exhibit 2024	FDA, "Transcript: Thalidomide: Potential Benefits and Risk Open Public Scientific Workshop;" (1997).
Exhibit 2025	Warren, R. "TVAC's Position On The Return Of Thalidomide, Living In A World with THALIDOMIDE: A New Reality;" (1998).
Exhibit 2026	Delaware Department of State: Division of Corporations, "Coalition for Affordable Drugs"
Exhibit 2027	Delaware Department of State: Division of Corporations, "Coalition for Affordable Drugs VI LLC – Entity Details"
Exhibit 2028	The Wall Street Journal, "New Hedge Fund Strategy: Dispute the Patent, Short the Stock;" (2015).
Exhibit 2029	Business Insider, "Hedge Fund Manager Kyle Bass Is Going After Big Pharma And Its 'BS Patents;" (2015).
Exhibit 2030	Hayman Capital Management, L.P. June 2015 Form ADV Part 2A Brochure
Exhibit 2031	The Wall Street Journal, "Innovate or Else: Kyle Bass Strikes Again and Challenges Shire Patents;" (2015).
Exhibit 2032	Thalomid [®] July 1998 Package Insert
Exhibit 2033	Dallas Observer "Dallas' Erich Spangenberg is Very Proud to be America's Biggest Patent Troll;" (2013).
Exhibit 2034	January 2014 Spangenberg/IPNav email threatening IPRs
Exhibit 2035	January 2014 Spangenberg/IPNav threatened '501 patent IPR petition
Exhibit 2036	January 2014 Spangenberg/IPNav threatened '501 patent IPR declaration
Exhibit 2037	January 2014 Spangenberg/IPNav threatened '720 patent obviousness IPR petition
Exhibit 2038	January 2014 Spangenberg/IPNav threatened '720 patent obviousness IPR declaration
Exhibit 2039	January 2014 Spangenberg/IPNav threatened '720 patent anticipation IPR petition

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EXHIBIT NO.	DESCRIPTION
Exhibit 2040	January 2014 Spangenberg/IPNav threatened '720 patent anticipation IPR declaration
Exhibit 2041	January 2014 Spangenberg/IPNav patent family tree
Exhibit 2042	July 2014 IRDP email threatening IPRs
Exhibit 2043	July 2014 IRDP threatened '501 patent IPR petition
Exhibit 2044	July 2014 IRDP threatened '501 patent IPR declaration
Exhibit 2045	July 2014 IRDP threatened '720 patent obviousness IPR petition
Exhibit 2046	July 2014 IRDP threatened '720 patent obviousness IPR declaration
Exhibit 2047	July 2014 IRDP threatened '720 patent anticipation IPR petition
Exhibit 2048	July 2014 IRDP threatened '720 patent anticipation IPR declaration
Exhibit 2049	July 2014 IRDP patent family tree
Exhibit 2050	Law360, "Shire Drugs Are Next Targets of Hedge Fund's AIA Reviews;" (2015).
Exhibit 2051	Hayman Capital Management, L.P. "Statement of J. Kyle Bass Chief Investment Officer, Hayman Capital Management, L.P.;" (2015).
Exhibit 2052	Reuters, "U.S. hedge fund plans to take on big pharma over patents;" (2015).
Exhibit 2053	Pharma: The Catalyst, "What They Are Saying: Close Patent Loopholes That Threaten Innovation for Patients;" (2015).
Exhibit 2054 ¹	IP Watchdog, "Senator Coons – Patents Are about the American Dream;" (2015).
Exhibit 2055 ²	Declaration of Andrew S. Chalson in Support of Patent Owner Unopposed Motion for Pro Hac Vice Admission of Andrew S. Chalson
Exhibit 2056	Chart of Cited Prior Art prepared by CFAD's expert Dr. Jeffrey Fudin

¹ Exhibits 2001-2054 were previously filed and served on July 28, 2015.

² Exhibit 2055 was previously filed and served on November 25, 2015.

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EXHIBIT NO.	DESCRIPTION
Exhibit 2057	Listing of Cited Prior Art prepared by CFAD's expert Dr. Jeffrey Fudin
Exhibit 2058	Talsma, J. "New Clozapine REMS program changes monitoring, dispensing requirements" (2015)
Exhibit 2059	Declaration of Lourdes M. Frau, M.D., FAAP, FISPE
Exhibit 2060	Declaration of Joseph T. DiPiro, Pharm.D.
Exhibit 2061	01/07-08/2016 Deposition of Dr. Jeffery Fudin, Volumes 1&2
Exhibit 2062	Keravich, D. "Challenges of thalidomide distribution in a hospital setting" (1999)
Exhibit 2063	S.T.E.P.S. Patient Registration Form
Exhibit 2064	S.T.E.P.S. "Dear Pharmacist" Letter
Exhibit 2065	S.T.E.P.S. Pharmacy Registration Card
Exhibit 2066	Website Bio of Dr. Allen A. Mitchell, M.D., Director Slone Epidemiology Center, Boston University
Exhibit 2067	THALOMID [™] Package Insert (July 1998)
Exhibit 2068	Leonard, M. "Thalidomide returns, as do fears" (1997)
Exhibit 2069 ³	Declaration of John Freeman, Corporate VP, Head of Global Drug Safety and Risk Management, Celgene Corporation.
Exhibit 2070	Email from Celgene Corporation to Coalition for Affordable Drugs VI LLC (June 6, 2016)

³ Exhibits 2056-2069 were previously filed and served on February 12, 2016.

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