Paper No. \_\_\_ Filed: June 23, 2016

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 VI LLC

V.

Petitioner,

CELGENE CORPORATION
Patent Owner

Case IPR2015-01102 Patent 6,315,720

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



| EXHIBIT<br>NO. | DESCRIPTION   |
|----------------|---|
| Exhibit 2001   | Thalomid® June 2014 Package Insert  |
| Exhibit 2002   | Dr. V. Pannikar, WHO, "The Return of Thalidomide:<br>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 <sup>th</sup> Meeting of the Dermatologic and Ophthalmic Drugs Advisory |



| EXHIBIT<br>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,<br>Living In A World with THALIDOMIDE: A New Reality;"<br>(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   |



| EXHIBIT<br>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 <sup>1</sup> | IP Watchdog, "Senator Coons – Patents Are about the American Dream" (2015).  |
| Exhibit 2055              | 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   |
| Exhibit 2057              | Listing of Cited Prior Art prepared by CFAD's expert Dr. Jeffrey Fudin   |

<sup>&</sup>lt;sup>1</sup> Exhibits 2001-2054 were previously filed and served on July 29, 2015.



| EXHIBIT<br>NO.            | DESCRIPTION   |
|---------------------------|---|
| 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. Pharmacy Registration Card   |
| Exhibit 2064              | S.T.E.P.S. "Dear Pharmacist" Letter   |
| Exhibit 2065              | S.T.E.P.S. Patient Registration Form  |
| Exhibit 2066              | THALOMID™ Package Insert (July 1998)  |
| Exhibit 2067              | Leonard, M. "Thalidomide returns, as do fears" (1997)   |
| Exhibit 2068 <sup>2</sup> | Declaration of John Freeman, Corporate VP, Head of Global Drug<br>Safety and Risk Management, Celgene Corporation |
| Exhibit 2069              | Email from Celgene Corporation to Coalition for Affordable Drugs VI LLC (June 6, 2016)                            |

<sup>&</sup>lt;sup>2</sup> Exhibits 2054-2068 were previously filed and served on February 12, 2016.



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