

February 27, 2018

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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Inter Partes Review IPR2018-00625 (U.S. Patent No. 9,492,392)
Exhibit Cover Letter Per 37 C.F.R. § 42.6(e)(4)(ii)

Dear Patent Trial and Appeal Board:

This transmittal letter identifies Exhibits 1001-1063, being filed concurrently with the present Petition for *Inter Partes* Review. Pursuant to 37 C.F.R. § 42.6(e)(4)(ii), the Certificate of Service attached to the end of the Petition for *Inter Partes* Review filed herewith, incorporates Exhibits 1001-1063, as listed below:

Exhibit #	Reference
1001	U.S. Patent No. 9,492,392 (“the ’392 Patent”)
1002	U.S. Patent No. 1,479,293 (“the ’293 Patent”)
1003	Finding of Facts and Conclusion of Law, <i>Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC</i> , No. 13-cv-3372 (S.D.N.Y. Apr. 8, 2015) (“SDNY Decision”)
1004	U.S. Patent No. 8,337,888 (“the ’888 Patent”)
1005	Patent Owners’ Resp. to Petition for <i>Inter Partes</i> Review Under 35 U.S.C. § 313 and 37 C.F.R. § 42.107, <i>Amneal v. Purdue</i> , IPR2016-01027 (P.T.A.B. Feb. 8, 2017)
1006	U.S. Patent No. 9,060,976 (“the ’976 Patent”)
1007	Patent Owners’ Resp. to Petition for <i>Inter Partes</i> Review Under 35 U.S.C. § 313 and 37 C.F.R. § 42.107, <i>Amneal v. Purdue</i> IPR20016-01413 (P.T.A.B. Apr. 10, 2017)
1008	U.S. Patent No. 9,034,376
1009	Finding of Facts and Conclusion of Law, <i>Purdue Pharma L.P. et al. v. Teva Pharms. USA, Inc.</i> , No. 11-cv-2037, 11-cv-5083 (S.D.N.Y. Jan. 14, 2014) (“SDNY II”), <i>aff’d</i> 2014-1306, -1307 (Fed. Cir. Feb. 1, 2016)
1010	U.S. Patent No. 8,114,383 (“the ’383 Patent”)
1011	Patrick Radden Keefe, <i>The Family that Built an Empire of Pain</i> , <i>The New Yorker</i> , Oct. 30, 2017
1012	Christopher Glazek, <i>The Secretive Family Making Billions from the Opioid Crisis</i> (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/

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Exhibit #	Reference
1013	Harriet Ryan <i>et al.</i> , ‘You want a description of hell?’ <i>OxyContin’s 12-Hour Problem</i> (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/
1014	Harriet Ryan <i>et al.</i> , <i>More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew</i> (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/
1015	Harriet Ryan <i>et al.</i> , <i>OxyContin goes global — “We’re only just getting started”</i> (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/
1016	U.S. Patent No. 5,508,042 (“Oshlack 1”)
1017	U.S. Patent Publication No. 2003/0068375 (“Wright”)
1018	Complaint, <i>Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals, LLC</i> , No. 17-cv-00210 (D. Del. Mar. 1, 2017), ECF No. 1
1019	Declaration of Benjamin Oshlack (Ex. 2097 in IPR2016-01027 and -01028)
1020	Complaint, <i>Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals, LLC</i> , No. 15-cv-01152 (D. Del. Dec. 15, 2015, ECF No. 1)
1021	Complaint, <i>Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals, LLC</i> , No. 17-cv-01421 (D. Del. Oct. 10, 2017, ECF No. 1)
1022	Complaint, <i>Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals, LLC</i> , No. 18-cv-00051 (D. Del. Jan. 3, 2018, ECF No. 1)
1023	Complaint, <i>Purdue Pharma L.P. et al. v. Kashiv Pharma, LLC</i> , No. 18-cv-00052 (D. Del. Jan. 3, 2018, ECF No. 1)
1024	U.S. Publication No. 2005/0031546 (“Bartholomaus”)
1025	U.S. Patent No. 6,488,963 (“McGinity”)
1026	U.S. Publication No. 2004/0170680 (“Oshlack 2”)
1027	U.S. Patent No. 5,273,758 (“Royce”)
1028	Antonio Moroni & Isaac Ghebre-Sellassie, <i>Application of Poly(Oxyethylene) Homopolymers in Sustained Release Solid Formulations</i> , 21(12) <i>Drug Development & Industrial Pharmacy</i> (1995), at 1411-28 (“Moroni”)
1029	Zezhi J. Shao <i>et al.</i> , <i>Effects of Formulation Variables and Post-compression Curing on Drug Release from a New Sustained-Release Matrix Material: Polyvinylacetate-Povidone</i> , 6(2) <i>Pharmaceutical Development & Technology</i> (2001), at 247-54 (“Shao”)
1030	Declaration of Hossein Omidian, Ph.D. (“Omidian Declaration”)
1031	<i>Curriculum Vitae</i> of Hossein Omidian, PhD
1032	U.S. Provisional Application No. 60/840,244
1033	U.S. Patent Application No. 14/729,634 (“the ’634 Application”)
1034	Serial No. 14/729,634, Non-Final Office Action, August 27, 2015
1035	Serial No. 14/729,634, Amendment, November 18, 2015

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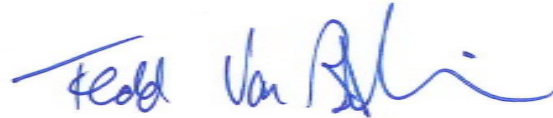
Exhibit #	Reference
1036	Declaration of Richard O. Mannion Under C.F.R. § 1.132, March 27, 2015
1037	Serial No. 14/729,634, Supplemental Amendment, February 16, 2016
1038	Serial No. 14/729,634, Final Office Action, May 24, 2016
1039	Serial No. 14/729,634, Amendment After Final, June 3, 2016
1040	Serial No. 14/729,634, Notice of Allowability
1041	Mai <i>et al.</i> , <i>Effects of cold extrusion and heat treatment on the mechanical properties of polypropylene</i> , 15(86) <i>Matériaux et Constructions</i> (1982), at 99-106
1042	Hatim S. AlKhatib <i>et al.</i> , <i>Effects of Thermal Curing Conditions on Drug Release from Polyvinyl Acetate-Polyvinyl Pyrrolidone Matrices</i> , 11(1) <i>AAPS PharmSciTech</i> (Mar. 2010), at 253-66
1043	Patience Mpofo <i>et al.</i> , <i>Temperature influence of nonionic polyethylene oxide and anionic polyacrylamide on flocculation and dewatering behavior of kaolinite dispersions</i> , 271 <i>J. of Colloid & Interface Sci.</i> (Mar. 2004), at 145-56
1044	1999 PDR - OxyContin
1045	Dow 2002 product catalog
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1047	Handbook of pharmaceutical excipients
1048	U.S. Pub. No. 2004/0037883 (“Zhou”)
1049	A. Apicella <i>et al.</i> , <i>Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release</i> 14(2) <i>Biomaterials</i> (1993), at 83-90
1050	Omelczuk <i>et al.</i> , <i>The influence of thermal treatment on the physical-mechanical and dissolution properties of tablets containing poly(DL-lactic acid)</i> <i>Pharmaceutical Research</i> , Vol. 10, No. 4 (1993)
1051	U.S. Patent No. 5,639,476 (“Oshlack 3”)
1052	Kurt H. Bauer <i>et al.</i> , <i>Coated Pharmaceutical Dosage Forms</i> , Scientific Publishers Stuttgart (1998), at 86-87
1053	Serial No. 14/729,634 Suppl. Prelim. Amendment, Jan. 23, 2013
1054	Decision, Institution of <i>Inter Partes</i> Review 37 C.F.R. § 42.108, <i>Amneal v. Purdue</i> , IPR2016-01027 (P.T.A.B. Nov. 9, 2016), Paper No. 13
1055	Final Written Decision, <i>Amneal v. Purdue</i> , IPR2016-01028 (P.T.A.B. Nov. 8, 2016), Paper No. 47
1056	Final Written Decision, <i>Amneal v. Purdue</i> , IPR2016-01027 (P.T.A.B. Nov. 8, 2016), Paper No. 48

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Exhibit #	Reference
1057	Johannes Bartholomäus, PhD <i>et al.</i> , <i>New Abuse Deterrent Formulation (ADF) Technology for Immediate-Release Opioids</i> , Abuse Deterrent Technology, 13(8) Drug Development & Delivery (October 2013)
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1060	<i>Physicochemical properties and mechanism of drug release from ethyl cellulose matrix tablets prepared by direct compression and hot-melt extrusion</i> , 269 International Journal of Pharmaceutics (2004) 269, 509-522 (“Crowley”)
1061	U.S. Publication No. 2005/0233062 (“Hossainy”)
1062	U.S. Patent No. 5,160,753 (“Edgren”)
1063	US 2007/0190142 (“Breitenbach”)

Respectfully submitted,

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TVB/dmf