

UNITED STATES PATENT AND TRADEMARK OFFICE PATENT

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,

*Petitioner,*

v.

NOVARTIS PHARMACEUTICALS CORPORATION

*Patent Owner.*

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Case: IPR2017-01592<sup>1</sup>

Patent No. 8,410,131

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**PETITIONER'S UPDATED EXHIBIT LIST DATED AUGUST 10, 2018**

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<sup>1</sup> IPR2018-0007 has been joined to this proceeding and the proceeding has been terminated as to Petitioner Breckenridge Pharmaceutical Inc.

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 8,410,131 (“the ‘131 patent”)
1002	PCT Published Application No. WO 01/51049 A1, <i>O-Methylated Rapamycin Derivatives for Alleviation and Inhibition of Lymphoproliferative Disorders</i> , to Wasik et al. (“Wasik”)
1003	PCT Published Application No. WO 00/33878 A2, <i>Macrolides</i> , to Navarro et al. (“Navarro”)
1004	Crowe et al., <i>Absorption and Intestinal Metabolism of SDZ-RAD and Rapamycin in Rats</i> , Drug Metab. Disp. (1999), 27(5): 627-632 (“Crowe”)
1005	Luan et al., <i>Sirolimus Prevents Tumor Progression: mTOR Targeting for the Inhibition of Neoplastic Progression</i> , Am. J. Transplant. (2001) 1 Suppl 1,243 (Abstr. No. 428) (“Luan”)
1006	Hidalgo et al., <i>The Rapamycin-sensitive Signal Transduction Pathway as a Target for Cancer Therapy</i> , Oncogene (2000) 19(56): 6680-6686 (“Hidalgo”)
1007	Alexandre et al., <i>CCI-779, A new Rapamycin Analog, Has Antitumor Activity at Doses Including Only Mild Cutaneous Effects and Mucositis: Early Results of an Ongoing Phase I Study</i> , Clin. Cancer Res. Suppl. (1999) 5: 3730s, Abstr. No. 7 (AACR- NCI-EORTC International Conference, November 16-19, 1999 held in Washington, DC) (“Alexandre”)
1008	Schuler et al., <i>SDZ RAD, A New Rapamycin Derivative</i> , Transplantation (1997) 64(1): 36-42 (“Schuler”)

Exhibit Number	Exhibit Description
1009	Neumayer et al., <i>Entry-into-human Study with the Novel Immunosuppressant SDZ RAD in Stable Renal Transplant Patients</i> , Br. J. Clin. Pharmacol. (1999) 48(5): 694-703 (“Neumayer”)
1010	Declaration of Allan J. Pantuck, M.D. in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,410,131
1011	RAPAMUNE <sup>®</sup> (sirolimus) Oral Solution RAPAMUNE <sup>®</sup> Approval Letter and approved labeling
1012	Great Britain patent application (GB 0104072.4, “GB ‘072” or “the ‘072 priority application”)
1013	Great Britain patent application (GB0124957.2, “GB ‘957” or “the ‘957 priority application”)
1014	International Patent Application No. PCT/EP02/01714 (“the ‘714 PCT Application”)
1015	IPR Final Rules
1016	Dancey, J. E., <i>Rapamycin-Sensitive Signal-Transduction Pathways: Protein Translation Control of Cell Proliferation</i> , ASCO Educational Book (2000) 68-75 (“Dancey”)
1017	Sorbera et al, <i>SDZ-RAD</i> , Drugs of the Future (1999) 24(1): 22-29 (“Sorbera”)
1018	U.S. Patent No. 5,362,718, to Skotnicki et al. (“Skotnichich ‘718”)
1019	U.S. Patent No. 5,665,772 to Cottens et al. (“Cottens ‘772 patent”)

Exhibit Number	Exhibit Description
1020	Sedrani et al., <i>Chemical Modification of Rapamycin: The Discovery of SDZ RAD</i> , Transplantation Proc.(1998) 30(5): 2192-2194 (“Sedrani”)
1021	PCT Published Application No. WO 97/47317 A1, Combination of a Somatostatin Analogue and a Rapamycin, to G. Weckbecker (“Weckbecker”)
1022	U.S. Patent No. 6,331,547, Water Soluble SDZ RAD Esters, which issued to Zhu et al. on December 18, 2001 from U.S. Provisional Patent Application No. 60/183,035 filed on August 18, 1999 to Zhu (“Zhu ‘547 patent”)
1023	U.S. Patent Application Publication No. 2002/0183239 A1, Antineoplastic Combinations, which published on December 5, 2002 from an application filed on April 6, 2001, to Gibbons (“Gibbons US ‘239”)
1024	U.S. Patent Application Publication No. 2003/0008923 A1, Antineoplastic Combinations, which published on January 9, 2003 from an application filed on June 1, 2001 to Dukart (“Dukart US ‘923”)
1025	Flowcharts for 35 U.S.C. § 102(e) Dates (“102(e) Date Flowchart”)
1026	Published Application No. WO 94/09010 A1, O-Alkylated Rapamycin Derivatives and their use, particularly as immunosuppressants, to Cottens et al. (“Cottens WO ‘010”)
1027	Selected portions of Prosecution History Documents (“May 10, 2010 Amendment re. Cottens WO ‘010”)
1028	Curriculum Vitae of Allan J. Pantuck, M.D.

Exhibit Number	Exhibit Description
1029	2015 Orange Book,"35th Edition (2015) with respect to AFINITOR® ("2015 Orange Book ")
1030	Alexandre, Raymond, et al., La rapamycine et le CCI-779, Bull. Cancer (1999) 86(10): 808-811("Alexandre" and Raymond")
1031	Boni et al., <i>Pharmacokinetics of escalating doses of CCI-779 in Combination with 5-Fluorouracil and Leucovorin in Patients with Advanced Solid Tumors</i> , Eur. J. Cancer (2001) 37(Suppl. 6): S68 (Abstr. No. 242) (The 11 <sup>th</sup> ECCO October 21-25, 2001 meeting held in Lisbon, Portugal) ("Boni")
1032	Dinney et al., <i>Biology of Metastasis: Studies in Renal Cancer (17-24)</i> , in Principles and Practice of Genitourinary Oncology (Raghavan et al. eds., 1997) ("Dinney")
1033	Shi et al., <i>Rapamycin enhances Apoptosis and Increases Sensitivity to Cisplatin in Vitro</i> , Cancer Research (1995) 55(9): 1982-1988 ("Shi")
1034	Fosså et al., <i>Survival of Patients with Advanced Urothelial Cancer treated with Cisplatin-based Chemotherapy</i> , Brit. J. Cancer (1996) 74: 1655-1659 ("Fosså")
1035	Motzer et al., <i>Survival and Prognostic Stratification of 670 Patients with Advanced Renal Cell Carcinoma</i> , J. Clin. Oncol. (1999) 17(8): 2530-2540 ("Motzer et al.")
1036	PCT Published Application No. WO 02/40000 A2, <i>Use of CCI-779 as an Antineoplastic Agent</i> , to Dukart et al. ("Dukart WO '000")

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