

Filed on behalf of: Par Pharmaceutical, Inc.

Entered: August 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.

Petitioner

v.

NOVARTIS AG

Patent Owner

Case IPR2016-01479

U.S. Patent No. 9,006,224

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLY, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

PETITIONER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Petitioner Par Pharmaceutical, Inc. respectfully submits the following current exhibit list.

1001	U.S. Patent No. 9,006,224 (“the ’224 patent”), titled “Neuroendocrine Tumor Treatment”
1002	File History for the ’224 patent
1003	Declaration of Mark J. Ratain, M.D. in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,006,224 (“Ratain Decl.”)
1004	Curriculum Vitae of Mark J. Ratain, M.D.
1005	A. Boulay et al., <i>Antitumor efficacy of intermittent treatment schedules with the rapamycin derivative RAD001 correlates with Prolonged Inactivation of Ribosomal Protein S6 Kinase 1 in Peripheral Blood Mononuclear Cells</i> , 64 CANCER RES. 252 (2004) (“Boulay 2004”)
1006	E. Brown et al., <i>A mammalian protein targeted by G1-arresting rapamycin-receptor complex</i> , 369 NATURE 756 (1994) (“Brown”)
1007	P. Buetow et al., <i>Islet cell tumors of the Pancreas: Pathologic-Imaging Correlation Among Size, Necrosis and Cysts, Calcification, Malignant Behavior, and Functional Status</i> , 165 AM. J. ROENTGENOLOGY 1175 (1995)
1008	Center for Drug Evaluation & Research, <i>Approval Package for NDA 021083 (Rapamune)</i> , Food & Drug Administration (Sept. 15, 1999)
1009	J. Dancey, <i>Clinical development of mammalian target of rapamycin inhibitors</i> , 16 HEMATOLOGY/ONCOLOGY CLINICS OF N. AM. 1101 (2002) (“Dancey”)
1010	M. De Jong et al., <i>Therapy of neuroendocrine tumors with radiolabeled somatostatin-analogues</i> , 43 Q. J. NUCLEAR MED. & MOLECULAR IMAGING 356 (1999) (“De Jong”)
1011	I. Duran et al., <i>A Phase II Trial of Temsirolimus in Metastatic Neuroendocrine Carcinomas (NECs)</i> , 23 SUPPL. J. CLIN. ONCOL. 3096 (2005) (“Duran”)

1012	J. Dutcher, <i>Mammalian target of rapamycin inhibition</i> , 10 CLIN. CANCER RES. 6382s (2004) (“Dutcher”)
1013	C. P. Eng et al., <i>Activity of Rapamycin (AY-22,989) Against Transplanted Tumors</i> , 37 J. ANTIBIOTICS 1231 (1984) (“Eng”)
1014	M. Grewe et al., <i>Regulation of Cell Growth and Cyclin D1 Expression by the Constitutively Active FRAP-p70^{S6K} Pathway in Human Pancreatic Cancer Cells</i> , 59 CANCER RES. 3581 (1999) (“Grewe”)
1015	M. Guba et al., <i>Rapamycin inhibits primary and metastatic tumor growth by antiangiogenesis: involvement of vascular endothelial growth factor</i> , 8 NATURE MED. 128 (2002) (“Guba”)
1016	M. Hidalgo et al., <i>The rapamycin-sensitive signal transduction pathway as a target for cancer therapy</i> , 19 ONCOGENE 6680 (2000) (“Hidalgo”)
1017	S. Huang et al., <i>Inhibitors of mammalian target of rapamycin as novel antitumor agents: from bench to clinic</i> , 3 CURRENT OPINION IN INVESTIGATIONAL DRUGS 295 (2002) (“Huang 2002”)
1018	S. Huang et al., <i>Rapamycins: Mechanism of Action and Cellular Resistance</i> , 2 CANCER BIOL. & THER. 222 (2003) (“Huang 2003”)
1019	M. Levy and M. Wiersema, <i>Pancreatic neoplasms</i> , 15 GASTROINTESTINAL ENDOSCOPY CLIN. N. AM. 117 (2005) (“Levy”)
1020	G. Kaltsas et al., <i>The Diagnosis and Medical Management of Advanced Neuroendocrine Tumors</i> , 25 ENDOCRINE REV. 458 (2004) (“Kaltsas”)
1021	R. Martel et al., <i>Inhibition of the immune response by rapamycin, a new antifungal antibiotic</i> , 55 CAN. J. PHYSIOL. PHARMACOL. 48 (1977) (“Martel”)
1022	R. Morris, <i>Rapamycins: Antifungal, Antitumor, Antiproliferative, and Immunosuppressive Macrolides</i> , 6 TRANSPLANTATION REV. 39 (1992) (“Morris”)
1023	C. Moertel et al., <i>Streptozocin-Doxorubicin, Streptozocin-Fluorouracil, or Chlorozotocin in the Treatment of Advanced Islet-Cell Carcinoma</i> , 326 NEW ENG. J. MED. 519 (1992) (“Moertel”)

1024	M. Neshat et al., <i>Enhanced sensitivity of PTEN-deficient tumors to inhibition of FRAP/mTOR</i> , 98 PNAS 10314 (2001) (“Neshat”)
1025	K. Öberg, <i>Chemotherapy and biotherapy in the treatment of neuroendocrine tumours</i> , 12 ANN. ONCOL. S111 (2001) (“Öberg 2001”)
1026	K. Öberg, <i>Management of neuroendocrine tumors</i> , 15 ANN. ONCOLOGY iv293 (2004)
1027	K. Öberg, <i>Treatment of neuroendocrine tumors of the gastrointestinal tract</i> , 27 ONCOLOGIA 57 (2004) (“Öberg 2004”)
1028	K. Öberg and B. Eriksson, <i>Endocrine tumours of the pancreas</i> , 19 BEST PRACTICE & RES. CLIN. GASTROENT. 753 (2005) (“Öberg & Eriksson”)
1029	A. O’Donnell et al., <i>A phase I study of the oral mTOR inhibitor RAD001 as a monotherapy to identify the optimal biologically effective dose using toxicity, pharmacokinetic (PK) and pharmacodynamics (PD) endpoints in patients with solid tumors</i> , 22 PROC. AM. SOC’Y OF CLINICAL ONCOLOGY 200(803ab) (2003) (“O’Donnell”)
1030	T. O’Reilly et al., <i>In vivo activity of RAD001, an orally active rapamycin derivative, in experimental tumor models</i> , 43 PROC. AM. ASS’N OF CANCER RES. 71 (Abstract #359) (2002) (“O’Reilly”)
1031	A. Perren, et al., <i>Mutation and expression analyses reveal differential subcellular compartmentalization of PTEN in endocrine pancreatic tumors compared to normal islet cells</i> , 157 AM. J. PATHOLOGY 1097 (2000) (“Perren”)
1032	U. Plöckinger et al., <i>Guidelines for the Diagnosis and Treatment of Neuroendocrine Gastrointestinal Tumours</i> , 80 NEUROENDOCRINOLOGY 394 (2004) (“NET Guidelines”)
1033	R. Rao et al., <i>Mammalian Target of Rapamycin (mTOR) Inhibitors as Anti-Cancer Agents</i> , 4 CURR. CANCER DRUG TARGETS 621 (2004) (“Rao”)
1034	C. Sawyers, <i>Will mTOR inhibitors make it as cancer drugs?</i> , 4 CANCER CELL 343 (2003) (“Sawyers”)

1035	S. Schreiber, <i>Chemistry and biology of the immunophilins and their immunosuppressive ligands</i> , 251 SCIENCE 283 (1991) (“Schreiber”)
1036	W. Schuler et al., <i>SDZ RAD, a new rapamycin derivative: pharmacological properties in vitro and in vivo</i> , 64 TRANSPLANTATION 36 (1997) (“Schuler”)
1037	A. Tolcher, <i>Novel therapeutic molecular targets for prostate cancer: the mTOR signaling pathway and epidermal growth factor receptor</i> , 171 J. UROLOGY S41 (2004) (“Tolcher”)
1038	J. Tabernero et al., <i>A phase I study with tumor molecular pharmacodynamic (MPD) evaluation of dose and schedule of the oral mTOR-inhibitor Everolimus (RAD001) in patients (pts) with advanced solid tumors</i> , 23 J. CLINICAL ONCOLOGY 3007 (2005) (“Tabernero”)
1039	S. Vignot et al., <i>mTOR-targeted therapy of cancer with rapamycin derivatives</i> , 16 ANN. ONCOL. 525 (2005) (“Vignot”)
1040	U.S. Patent No. 3,929,992 (“the ’992 patent”)
1041	U.S. Patent No. 4,650,803 (“the ’803 patent”)
1042	U.S. Patent No. 4,885,171 (“the ’171 patent”)
1043	U.S. Patent No. 5,100,883 (“the ’883 patent”)
1044	U.S. Patent No. 5,206,018 (“the ’018 patent”)
1045	U.S. Patent No. 5,233,036 (“the ’036 patent”)
1046	U.S. Patent No. 5,362,718 (“the ’718 patent”)
1047	U.S. Patent No. 5,391,730 (“the ’730 patent”)
1048	U.S. Patent No. 5,665,772 (“the ’772 patent”)
1049	U.S. Patent No. 7,091,213 (“the ’213 patent”)
1050	U.S. Patent No. 8,410,131 (“the ’131 patent”)

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