

Filed On Behalf Of:
Novartis AG

By:
Nicholas N. Kallas
NKallas@fchs.com
ZortressAfinitorIPR@fchs.com
(212) 218-2100

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

Patent No. 9,006,224

PATENT OWNER'S EXHIBIT LIST 8

Exhibit	Description	Abbreviation
2001	Expert Declaration Of Matthew H. Kulke, M.D., M.M.Sc. (November 18, 2016)	Kulke Decl.
2002	<i>Curriculum Vitae</i> of Matthew H. Kulke, M.D., M.M.Sc. (May 20, 2016)	Kulke C.V.
2003	Seeley, R. R., Stephens, T.D., & Tate, P., <i>Anatomy & Physiology</i> , 3rd Edition, pages 585 – 586 (1995)	Seeley
2004	<i>Reserved</i>	
2005	Laughlin, E.H., <i>Coming To Terms With Cancer: A Glossary Of Cancer-Related Terms</i> , page 4 (2002)	Laughlin Cancer Glossary
2006	<i>Reserved</i>	
2007	<i>Reserved</i>	
2008	Motzer, R.J. & Russo, P., “Systemic Therapy For Renal Cell Carcinoma,” <i>J. Urology</i> 163:408-417 (2000)	Motzer
2009	<i>Reserved</i>	
2010	Pazdur, R., <i>et al.</i> (eds.), Chapters 6, 11, 14-16, 19, 25, <i>Cancer Management: A Multidisciplinary Approach: Medical, Surgical, & Radiation Oncology</i> , 9th Edition (2005)	Pazdur

2011	Kouvaraki, M.A. <i>et al.</i> , “Fluorouracil, Doxorubicin, And Streptozocin In The Treatment Of Patients With Locally Advanced And Metastatic Pancreatic Endocrine Carcinomas,” <i>J. Clin. Oncol.</i> 22(23):4762-4771 (2004)	Kouvaraki
2012	Delaunoy, Th., <i>et al.</i> , “The Doxorubicin-Streptozotocin Combination For The Treatment Of Advanced Well-Differentiated Pancreatic Endocrine Carcinoma: A Judicious Option?,” <i>Eur. J. Cancer</i> 40:515-520 (2004)	Delaunoy
2013	Kulke, M.H., Chapter 110, “Neuroendocrine Cancer,” <i>Clinical Hematology and Oncology: Presentation, Diagnosis and Treatment</i> (Furie, B., <i>et al.</i> eds. 2003)	Kulke 2003a
2014	Kulke, M.H. <i>et al.</i> , “A Phase II Trial Of Gemcitabine For Metastatic Neuroendocrine Tumors,” <i>Cancer</i> 101(5): 934-939 (2004)	Kulke 2004
2015	Margolin, K. <i>et al.</i> , “CCI-779 In Metastatic Melanoma: A Phase II Trial Of The California Cancer Consortium,” <i>Cancer</i> 104(5): 1045-1048 (2005)	Margolin

2016	“Novartis Drug Afinitor Is First Treatment For Advanced Pancreatic NET To Provide Overall Survival Of More Than 3.5 Years In Phase III Trial,” <i>Novartis Institutes For Biomedical Research</i> (September 27, 2014)	Novartis Press Release
2017	Ritschel, W.A., <i>Handbook of Basic Pharmacokinetics</i> , 4th Edition, pages 6-7, 264-267 (1992)	Ritschel
2018	Heitz, Ph.U., <i>et al.</i> , Chapter 4, “Tumours Of The Endocrine Pancreas,” <i>World Health Organization Classification of Tumours, Pathology and Genetics, Tumours of Endocrine Organs</i> , pages 177-182 (DeLellis, R.A. <i>et al.</i> , eds. 2004)	WHO 2004
2019	Physicians’ Desk Reference, 59th Edition (2005), pages 1844-1849 (Entry for Gemzar® (Gemcitabine HCl))	Gemzar® Prescribing Information 2005
2020	Kulke, M.H. & Mayer, R.J., “Carcinoid Tumors,” <i>N. Eng. J. Med.</i> 340(11): 858-868 (1999)	Kulke 1999
2021	Gennaro, A.R. (Ed.), <i>Remington’s</i> , 18th Edition, pages 726-730 (1990)	Remington’s
2022	Yao, J.C. <i>et al.</i> , “Everolimus For Advanced Pancreatic Neuroendocrine Tumors,” <i>N. Eng. J. Med.</i> 364(6): 514-523 (2011)	Yao 2011

2023	Kola, I. & Landis, J., “Can The Pharmaceutical Industry Reduce Attrition Rates?,” <i>Nat. Rev. Drug Discov.</i> , 3:711-715 (2004)	Kola & Landis
2024	Excerpts of Transcript of Trial Testimony of M. Ratain, <i>Pfizer Inc. et al. v. Mylan Pharms. Inc.</i> , (C.A. No. 10-528-GMS), (D. Del. November 29, 2012), Pages 778-79, 950, 995	Ratain Trial Tr. I
2025	Excerpts of Transcript of Trial Testimony of M. Ratain, <i>Novartis v. Breckenridge, Roxane and Par</i> (C.A. Nos. 14-1043-RGA, 14-1196-RGA and 14-1289-RGA) (D. Del. August 31, 2016), Pages 769-772, 957, 993-94, 1003, 1010, 1012, 1014	Ratain Trial Tr. II
2026	Excerpts of Transcript of Deposition of M. Ratain, <i>Novartis v. Breckenridge, Roxane and Par</i> (C.A. Nos. 14-1043-RGA, 14-1196-RGA and 14-1289-RGA) (D. Del. Apr. 11, 2016), Pages 1-5, 34, 156, 340	Ratain Dep. Tr. I
2027	Dancey, J.E., “Inhibitors Of The Mammalian Target Of Rapamycin,” <i>Expert Opin. Investig. Drugs</i> 14(3): 313-328 (2005)	Dancey 2005
2028	Duran, I, <i>et al.</i> , “A Phase II Clinical And Pharmacodynamic Study Of Temsirolimus In Advanced Neuroendocrine Carcinomas,” <i>British J. of Cancer</i> 95(9): 1148-1154 (2006)	Duran 2006

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