

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.,
ARGENTUM PHARMACEUTICAL LLC, AND
WEST-WARD PHARMACEUTICALS
INTERNATIONAL LIMITED
Petitioners,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-01479¹
Patent No. 9,006,224

PATENT OWNER'S EXHIBIT LIST 9

¹ Argentum Pharmaceutical LLC was joined as a party to this proceeding via a Motion for Joinder in IPR2017-01063; West-Ward Pharmaceuticals International Limited was joined as a party via a Motion for Joinder in IPR2017-01078.

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

<p>2011</p>	<p>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)</p>	<p>Kouvaraki</p>
<p>2012</p>	<p>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)</p>	<p>Delaunoy</p>
<p>2013</p>	<p>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)</p>	<p>Kulke 2003a</p>
<p>2014</p>	<p>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)</p>	<p>Kulke 2004</p>
<p>2015</p>	<p>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)</p>	<p>Margolin</p>

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.