UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED Petitioner
v. NOVARTIS PHARMACEUTICALS CORPORATION
Patent Owner
Case IPR2018 U.S. Patent No. 8,410,131

PETITION FOR INTER PARTES REVIEW **OF U.S. PATENT NO. 8,410,131**



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		1.	"Inhibiting Growth of Solid Excretory System Tumors in a Subject"	
		2.	"advanced solid excretory system tumor"	
		3.	"kidney tumor"	
		4.	"unit dosage form"	
IX.			AL BACKGROUND AND STATE OF THE ART AT	19



	A.	Schuler teaches that everolimus shares the same mechanism of action as rapamycin, and everolimus exhibits improved properties compared to rapamycin	2
	В.	Crowe discloses that everolimus shares the same mechanism of action as rapamycin, and everolimus exhibits an improved oral absorption profile compared to rapamycin	4
	C.	Neumayer teaches that a therapeutically effective dosage amount of everolimus is well-tolerated in human patients24	4
	D.	Alexandre teaches that temsirolimus, like rapamycin, is an mTOR inhibitor, and temsirolimus inhibits growth of advanced solid excretory system tumors.	5
	E.	Hidalgo teaches that rapamycin and temsirolimus are mTOR inhibitors, the antitumor activity associated with rapamycin and temsirolimus is due to mTOR inhibition, and temsirolimus inhibits growth of advanced solid excretory system tumors20	6
	F.	Luan teaches that sirolimus inhibits growth of advanced kidney tumors	7
	G.	Wasik teaches that everolimus inhibits growth of advanced kidney tumors.	8
	H.	Navarro teaches that pharmaceutical compositions containing everolimus in an amount of 10 mg are useful to treat tumors3	1
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	D.	Ground 3: Claims 1-3 and 5-9 of the '131 patent are invalid under 35 U.S.C. § 103(a) on the ground that they are rendered obvious by the combination of Wasik, Navarro, Crowe, and Luan.	4
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		obvious by the combination of Hidalgo, Alexandre, Crowe, Schuler, Neumayer, and Navarro	47
	F.	Ground 5: Claims 1-3 and 5-9 of the '131 patent are invalid under 35 U.S.C. § 103(a) on the ground that they are rendered obvious by the combination of Hidalgo, Alexandre, Crowe, Schuler, Neumayer, Navarro, and Luan.	56
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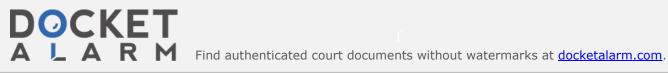


TABLE OF AUTHORITIES

	Page(s)
Cases	
In re Aller, 220 F.2d 454 (CCPA 1955)	33
In re Applied Materials, Inc., 692 F.3d 1289 (Fed. Cir. 2012)	33, 55
Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc., 713 F.3d 1369 (Fed. Cir. 2013)	61
Breckenridge Pharmaceutical Inc. v. Novartis Pharmaceuticals Corporation, IPR2017-01592	1
Cuozzo Speed Techs., LLC v. Lee, 136 S.Ct. 2131 (2016)	15
Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013)	61
Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC, 618 F.3d 1294 (Fed. Cir. 2010)	61
Glaxo Grp., Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004)	32
In re Gosteli, 872 F.2d 1008 (Fed. Cir. 1989)	12
Graham v. John Deere Co., 383 U.S. 1 (1966)	33
KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)	33
L.A. Biomedical Research Inst. at Harbor- UCLA Med. Ctr. v. Eli Lilly & Co., 849 F.3d 1049 (Fed. Cir. 2017)	13. 14



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