

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**

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iv
EXHIBIT LIST	viii
I. OVERVIEW	1
II. REQUIREMENTS FOR PETITION FOR <i>INTER PARTES</i> REVIEW.....	3
A. Grounds for Standing (37 C.F.R. § 42.104(a))	3
B. Notice of Lead and Backup Counsel and Service Information.....	3
C. Notice of Real-Parties-in-Interest (37 C.F.R. § 42.8(b)(1)).....	4
D. Notice of Related Matters (37 C.F.R. § 42.8(b)(2)).....	4
E. Fee for <i>Inter Partes</i> Review	5
F. Proof of Service.....	5
III. IDENTIFICATION OF CLAIMS BEING CHALLENGED (37 C.F.R. § 42.104(B))	5
IV. SUMMARY OF THE ARGUMENT	6
V. SUMMARY OF THE '131 PATENT	9
VI. PRIORITY DATE FOR CLAIMS 1-3 AND 5-9 OF THE '131 PATENT	12
VII. THE PERSON OF ORDINARY SKILL IN THE ART	14
VIII. CLAIM CONSTRUCTION	15
A. Applicable Law	15
B. Construction of Claim Terms	16
1. “Inhibiting Growth of Solid Excretory System Tumors in a Subject”	16
2. “advanced solid excretory system tumor”	17
3. “kidney tumor”	18
4. “unit dosage form”	18
IX. TECHNICAL BACKGROUND AND STATE OF THE ART AT THE TIME OF THE PURPORTED INVENTION	19

A.	Schuler teaches that everolimus shares the same mechanism of action as rapamycin, and everolimus exhibits improved properties compared to rapamycin.	22
B.	Crowe discloses that everolimus shares the same mechanism of action as rapamycin, and everolimus exhibits an improved oral absorption profile compared to rapamycin.	24
C.	Neumayer teaches that a therapeutically effective dosage amount of everolimus is well-tolerated in human patients.	24
D.	Alexandre teaches that temsirolimus, like rapamycin, is an mTOR inhibitor, and temsirolimus inhibits growth of advanced solid excretory system tumors.	25
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 tumors.	26
F.	Luan teaches that sirolimus inhibits growth of advanced kidney tumors.	27
G.	Wasik teaches that everolimus inhibits growth of advanced kidney tumors.	28
H.	Navarro teaches that pharmaceutical compositions containing everolimus in an amount of 10 mg are useful to treat tumors.	31
X.	CLAIMS 1-3 AND 5-9 ARE ANTICIPATED AND/OR OBVIOUS OVER THE PRIOR ART.	32
A.	Legal Background	32
B.	Ground 1: Claims 1-3 and 5-9 of the '131 patent are invalid under 35 U.S.C. § 102(a) or §102(e)(1) as anticipated by Wasik.	33
C.	Ground 2: 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 Wasik alone or in combination with Navarro.	41
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.	44
E.	Ground 4: 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, 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
XI.	OBJECTIVE INDICIA FAIL TO OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS.	58
XII.	CONCLUSION.....	62
	CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24.....	63
	CERTIFICATE OF SERVICE	64

TABLE OF AUTHORITIES

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

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.