

Paper No. \_\_\_\_  
Filed: May 25, 2016

Filed on behalf of: Mylan Pharmaceuticals Inc.  
By: Steven W. Parmelee  
Michael T. Rosato  
Jad A. Mills  
WILSON SONSINI GOODRICH & ROSATI  
701 Fifth Avenue, Suite 5100  
Seattle, WA 98104-7036

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,  
Patent Owner.

---

Case No. IPR2016-01101  
Patent No. RE38,551

---

**PETITION FOR INTER PARTES REVIEW OF  
U.S. PATENT NO. RE38,551**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8.....	1
A. Real Parties-In-Interest under 37 C.F.R. § 42.8(b)(1).....	1
B. Related Matters under 37 C.F.R. § 42.8(b)(2) .....	1
C. Lead and Backup Counsel under 37 C.F.R. § 42.8(b)(3).....	2
D. Service Information under 37 C.F.R. § 42.8(b)(4).....	2
II. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104 .....	2
A. Grounds For Standing Under 37 C.F.R. § 42.104(a) .....	2
B. Identification of Challenge, 37 C.F.R. § 42.104(b) .....	3
III. SUMMARY OF THE ‘551 PATENT .....	6
IV. PREVIOUS PETITION FILED BY OTHER UNRELATED PARTIES .....	7
V. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3).....	8
A. “Therapeutic Composition” in Claim 10 .....	8
B. “A Compound in the R Configuration” in Claim 1.....	10
VI. LEVEL OF SKILL AND KNOWLEDGE IN THE ART .....	12
A. Cortes (Ex. 1015).....	13
B. LeGall (1987) (Ex. 1008).....	13
C. Kohn 1991 (Ex. 1012).....	14
D. ’729 Patent (1991) (Ex. 1009).....	16
E. Kohn 1993 (Ex. 1017).....	17
F. Choi (1995) (Ex. 1010).....	18
G. ’301 Patent (1995) (Ex. 1019).....	19

VII.	CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY .....	20
A.	Ground 1A: Claims 1 and 3-8 Are Anticipated by LeGall.....	20
1.	New evidence establishes that LeGall is prior art.....	21
2.	LeGall discloses “racemic lacosamide” and R-lacosamide and therefore anticipates claims 1 and 3-8.....	22
B.	Ground 1B: Claims 2 and 9-13 Are Obvious Over LeGall And The ’729 Patent.....	23
1.	Claims 2 and 9 to “substantially” or “90%” pure R- enantiomer are obvious over LeGall and ’729 patent .....	23
2.	Claim 10 to a “therapeutic composition” is obvious over LeGall and the ’729 patent .....	27
3.	Claims 11-13 to methods of treatment are obvious over LeGall and ’729 patent.....	29
C.	Ground 2A: Claims 1-9 Are Obvious Over Choi and Kohn 1991 .....	32
1.	Choi and Kohn 1991 are prior art.....	32
2.	POSA had a reason to select Compound 2d of Choi as a lead compound.....	32
3.	POSA had a reason to modify the hydroxymethyl compound to a “ <i>functionalized oxygen</i> ” group.....	38
4.	POSA would have a reasonable expectation of success in making raceamic lacosamide and R lacosamide .....	39
D.	Ground 2B: Claims 10-13 Are Obvious Over Choi, Kohn 1991, And ’729 Patent .....	40
E.	Ground 3A: Claims 1-9 Are Obvious Over Kohn 1991 and Silverman .....	40
1.	Kohn 1991 and Silverman are prior art .....	41

2.	Activity data and bioisosterism suggest the change from methoxyamino to methoxymethyl (lacosamide).....	41
F.	Ground 3B: Claims 10-13 Are Obvious Over Kohn 1991, Silverman, and '729 Patent .....	44
G.	Ground 4A: Claims 1-9 Are Obvious Over Cortes and Kohn 1991 .....	44
1.	Cortes and Kohn 1991 are prior art .....	45
2.	POSA had a reason to select the methyl compound of Cortes or Kohn 1991 as a lead compound .....	45
3.	POSA had a reason to modify the methyl substituent to a methoxymethyl .....	46
H.	Ground 4B: Claims 10-13 Are Obvious Over Cortes, Kohn 1991, And '729 Patent .....	48
VIII.	THERE ARE NO SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS.....	48
IX.	THE CLAIMS ARE NOT ENTITLED TO THE PROVISIONAL FILING DATE .....	50
X.	FOUNDATIONS 1-4 ARE NON-CUMULATIVE OF EACH OTHER.....	51
XI.	THE BOARD SHOULD NOT DECLINE TO INSTITUTE BASED ON ITS DISCRETIONARY AUTHORITY UNDER 35 U.S.C. § 325(D).....	52
XII.	CLAIMS CHART FOR DEPENDENT CLAIM 2 AND 9-13.....	53
XIII.	CONCLUSION .....	54
XIV.	CERTIFICATE OF COMPLIANCE.....	55
XV.	PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.103 .....	56

...

Mylan Pharmaceuticals Inc. (“Petitioner”) requests that the Board institute *inter partes* review (“IPR”) of claims (1-13) of U.S. Patent No. RE 38,551 to Kohn (“the ’551 patent”) (Ex. 1001), and that these claims be canceled as unpatentable over the prior art. *Inter partes* review of claims 1-13 the ’551 patent, was instituted in IPR2016-00204 on May 23, 2016, based on a petition filed by Argentum Pharmaceuticals LLC (“Argentum”). For the sake of completeness and efficiency, the present Petition is a practical copy of the petition in IPR2016-00204. Petitioner is requesting however, that the Board institute only on the Grounds instituted in IPR2016-00204, *i.e.*, Grounds 3A and 3B as to claims 1-13, and not on Grounds 1A, 1B, 2A, 2B, 4A, and 4B. A motion for Joinder with IPR2016-00204 is being filed concurrently with this Petition.

**I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8**

**A. Real Parties-In-Interest under 37 C.F.R. § 42.8(b)(1)**

The following real parties-in-interest are identified: Mylan Pharmaceuticals Inc., the Petitioner in this matter and a wholly owned subsidiary of Mylan Inc.; Mylan Inc., which is an indirectly wholly owned subsidiary of Mylan N.V.; and Mylan N.V.

**B. Related Matters under 37 C.F.R. § 42.8(b)(2)**

On May 23, 2016, the Board instituted *inter partes* review of claims 1-13 of the ’551 patent in IPR2016-00204 based on a petition filed by Argentum. Previously, in IPR2014-01126, the Board denied institution of *inter partes* review of the ’551 patent based on a petition filed by Actavis, Inc., Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Amneal Pharmaceuticals of New

# 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.