

Filed: December 28, 2015

Filed on behalf of Petitioners,

Lupin Limited and Lupin Pharmaceuticals, Inc.

By: Christy G. Lea

Kerry S. Taylor

Benjamin Anger

KNOBBE, MARTENS, OLSON & BEAR, LLP

2040 Main Street, 14th Floor

Irvine, CA 92614

Tel.: (949) 760-0404

Fax: (949) 760-9502

Email: BoxLupin15B@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LIMITED
AND LUPIN PHARMACEUTICALS. INC.,
Petitioners

v.

iCEUTICA PTY LTD.

Patent Owner

Case No. TBD
U.S. Patent No. 9,017,721

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,017,721

TABLE OF CONTENTS

	Page No.
I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)	1
A. Real Party-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 Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)	2
D. Service Information Under 37 C.F.R. § 42.8(b)(4).....	2
E. Grounds for Standing Under 37 C.F.R. § 42.104(a).....	3
II. SUMMARY OF THE ISSUE PRESENTED.....	3
III. BACKGROUND AND STATE OF THE ART.....	4
A. Diclofenac Is a Well-Known NSAID	4
B. Skilled Artisans Knew to Reduce the Dose and Improve Bioavailability of Diclofenac	5
C. iCeutica’s Payne Application Disclosed Nanosized Diclofenac Acid.....	7
D. iCeutica’s Meiser Application Disclosed Nanosized Diclofenac Acid.....	8
IV. THE ’721 PATENT.....	9
A. The ’721 Patent Copies from Patent Owner’s Own Prior Art Publications, Meiser and Payne	10
B. The ’721 Patent Mentions Payne and Meiser, But Only in Passing.....	12
C. The ’721 Patent Teaches, But Does Not Claim, “Commercial Scale” Milling.....	12

TABLE OF CONTENTS
(cont'd)

	Page No.
D. Example 14 of the '721 Patent	14
1. The FDA Requires Dissolution Data	16
2. The Dissolution Test Conditions Came From the USP and FDA.....	17
E. The Prosecution History of the '721 Patent	21
V. THE IROKO AND ICEUTICA ADMISSIONS	24
A. The Iroko Prospectus Admits that Meiser Discloses iCeutica's Diclofenac Product	24
B. iCeutica's Press Release Admits Cammarano Covers iCeutica's Method of Making Zorvolex.....	27
C. Cammarano's Claims Are Further Evidence that the '721 Patent Adds Only a Dissolution Test	29
VI. LEVEL OF ORDINARY SKILL IN THE ART	30
VII. CONSTRUCTION OF THE CHALLENGED CLAIMS	30
A. "Wherein . . . When Tested" Clauses Deserve No Patentable Weight.....	32
1. "Wherein . . . When Tested" Clauses Do Not Add Substance to the Claims	32
2. The Dissolution Testing Is an Optional Condition in the Claims	35
VIII. SPECIFIC GROUNDS FOR CANCELLATION OF CLAIMS 1-24	36

TABLE OF CONTENTS
(cont'd)

	Page No.
A. The Grounds of Rejection Are Not Redundant.....	37
B. Ground 1: Claims 1-24 Would Have Been Obvious Over Meiser in View of the Novartis Package Insert	37
1. Claims 1 and 8.....	38
2. Claims 2-7 and 9-24.....	44
C. Ground 2: Claims 1-24 Would Have Been Obvious Over Meiser in View of the Novartis Package Insert, and in Further View of the USP and Chuasuwan	47
1. Claims 1 and 8.....	50
2. Claims 3-5 and 10-12.....	55
3. Claims 2, 6-7, 9, and 13-24.....	56
D. Ground 3: Claims 1-24 Would Have Been Obvious Over Meiser in View of the Novartis Package Insert, in View of the USP and Chuasuwan, and Further in View of Reiner.....	57
IX. SECONDARY CONSIDERATIONS, EVEN IF PRESENT, FAIL TO OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS.....	58
X. CONCLUSION.....	60

TABLE OF AUTHORITIES

Page No(s).

<i>In re Aller</i> , 220 F.2d 454 (C.C.P.A. 1955)	40, 49
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012)	39
<i>Ex Parte Berzofsky</i> , Appeal No. 1010-011270, 2011 WL 891756 (B.P.A.I. Mar. 10, 2011)	34
<i>In re Cuozzo Speed Techs., LLC</i> , 793 F.3d 1268 (Fed. Cir. 2015)	31
<i>In re Droge</i> , 695 F.3d 1334 (Fed. Cir. 2012)	59
<i>In re Geisler</i> , 116 F.3d 1465 (Fed. Cir. 1997)	41
<i>Hoffer v. Microsoft Corp.</i> , 405 F.3d 1326 (Fed. Cir. 2005)	33, 34
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	36, 49
<i>In re Kulling</i> , 897 F.2d 1147 (Fed. Cir. 1990)	41
<i>Minton v. Nat’l Ass’n of Securities Dealers, Inc.</i> , 336 F.3d 1373 (Fed. Cir. 2003)	33, 34, 35
<i>Not Dead Yet Mfg., Inc. v. Pride Sols., LLC</i> , No. 13 C 3418, 2015 WL 5829761 (N.D. Ill. Oct. 5, 2015)	34, 35
<i>Par Pharm., Inc. v. TWi Pharms., Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014)	49, 50, 55

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.