

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LIMITED AND LUPIN PHARMACEUTICALS INC.  
Petitioners

v.

iCEUTICA PTY LTD.  
Patent Owner

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Case IPR2016-00397  
Patent 8,999,387

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**PATENT OWNER iCEUTICA's  
PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

II. INTRODUCTION ..... 1

III. BACKGROUND ..... 4

IV. THE ‘387 PATENT ..... 9

    A. The ‘387 patent discloses diclofenac acid solid oral unit doses having improved dissolution profiles..... 9

    B. Particle size alone does not dictate the dissolution profile of the diclofenac acid solid oral unit dose ..... 10

    C. The ‘387 patent relies on a test for measuring the dissolution profile of a given diclofenac acid solid oral unit dose ..... 11

    D. During prosecution, the Examiner relied on the dissolution profile in allowing the ‘387 patent claims ..... 13

V. CLAIM CONSTRUCTION ..... 15

    A. The dissolution profile is entitled to patentable weight ..... 17

        1. The dissolution profile defines the diclofenac acid-containing solid oral unit dose that is the subject of the claimed method for treating pain ..... 18

        2. The ‘387 patent specification and prosecution history demonstrate that the dissolution profile is “an integral part of the invention” ..... 22

        3. The dissolution profile is not a necessary consequence of particle size..... 25

        4. The dissolution profile is not an optional condition in the claims ..... 26

        5. Giving the dissolution profile patentable weight is consistent with the District Court of Delaware’s construction of the claims..... 28

..

VI.	CLAIMS 1-24 ARE PATENTABLE OVER MEISER IN VIEW OF THE NOVARTIS PACKAGE INSERT .....	29
A.	Claims 1-24 are not obvious over Meiser in view of the Novartis Package Insert.....	30
B.	Claims 1-24 are not obvious over Meiser in view of the Novartis Package Insert, USP, and Chuasuwan.....	32
1.	The obviousness of the test conditions is irrelevant .....	34
2.	Meiser’s diclofenac acid particles would not inherently have the dissolution profile in the ‘387 claims measured under the conditions disclosed in USP and Chuasuwan .....	35
C.	Claims 1-24 are not obvious over Meiser in view of the Novartis Package Insert, USP, Chuasuwan, and Reiner.....	40
VII.	CONCLUSION .....	42

...

**LIST OF EXHIBITS**

Exhibit No.	Description
2001	Lupin's Answering Claim Construction Brief, C.A. No. 14-1515-SLR-SRF (Dec. 4, 2015)
2002	Amiji Declaration submitted in support of Lupin's Answering Claim Constr. Br., C.A. No. 14-1515-SLR-SRF (Dec. 4, 2015)
2003	Deposition of Mansoor Amiji, R.Ph., Ph.D.-December 18, 2015
2004	Memorandum Order, C.A. No. 14-1515-SLR-SRF (February 29, 2016)

**TABLE OF AUTHORITIES**

**CASES** **Page(s)**

*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) .. 3, 29, 32, 34, 41

*In re Cuozzo Speed Techs., LLC*, No. 2014-1301, slip op. at 10-19 (Fed. Cir. 2015) ..... 15, 16

*In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ..... 16

*Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 1330 (Fed. Cir. 2005) ..... 18, 22

*In re Kao*, 639 F.3d 1057, 1061-62, 1066-67 (Fed. Cir. 2011) ..... 18, 19, 20, 27

*Microprocessor Enhancement Corp. v. Texas Instruments, Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008) ..... 19, 20

*Dell, Inc. v. Acceleron, LLC*, No. 2015-1513, -1514, slip op. at 11-12 (Fed. Cir. Mar. 15, 2016) ..... 26

*In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981) ..... 30, 39

*Santarus Inc. v. Par Pharm. Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) ..... 35

*Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ..... 39

**REGULATIONS**

35 U.S.C. § 103..... 2, 30

35 U.S.C. § 112..... 12, 13

37 C.F.R. § 42.100(b) ..... 15

**PTAB DECISIONS**

*Ex Parte Berzofsky*, Appeal No. 2010-011270, 2011 WL 891756 (BPAI March 10, 2011)..... 20, 21

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