

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TORRENT PHARMACEUTICALS LIMITED
Petitioner

v.

UCB PHARMA GMBH
Patent Owner

Patent No. 6,858,650
Filing Date: November 15, 2000
Issue Date: February 22, 2005
Title: STABLE SALTS OF NOVEL DERIVATIVES
OF 3,3-DIPHENYLPROPYLAMINES

Inter Partes Review No. Unassigned

**PETITION FOR *INTER PARTES* REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.***

TABLE OF CONTENTS

| | Page |
|---|-------------|
| I. INTRODUCTION | 1 |
| II. MANDATORY NOTICES | 1 |
| A. Real Party in Interest | 1 |
| B. Related Matters | 1 |
| C. Fee | 2 |
| D. Designation of Lead Counsel and Request for Authorization | 2 |
| E. Service Information | 2 |
| F. Standing | 3 |
| III. STATEMENT OF RELIEF REQUESTED | 3 |
| IV. SUMMARY OF THE '650 PATENT AND CHALLENGED CLAIMS | 5 |
| V. CLAIM CONSTRUCTION | 6 |
| VI. TECHNICAL BACKGROUND AND STATE OF THE ART | 6 |
| A. The Person of Ordinary Skill in the Art of the '650 Patent | 6 |
| B. Before the Invention, Antimuscarinic Compounds Were Used to Treat Overactive Bladder Conditions | 6 |
| C. Prodrugs Were Known to Solve Active Compound Difficulties | 9 |
| D. Numerous Salt Forms Were Known for Compounds Similar to the Most Effective Overactive Bladder Drugs | 12 |
| VII. SCOPE AND CONTENT OF THE PRIOR ART | 13 |
| A. Skilled Artisans Had Ample Motivation to Focus on Optimizing 5- HMT to Obtain an Overactive Bladder Compound | 14 |
| 1. Postlind, the Detrol [®] Label, and Brynne 1998 Taught 5-HMT Was an Effective Compound for Overactive Bladder without Tolterodine | 14 |
| 2. Skilled Artisans Would Immediately Recognize the Benefit to Starting with their Knowledge of 5-HMT and Tolterodine and Not Other Compounds | 16 |

| | | |
|-------|--|----|
| B. | Bundgaard Taught Predictable Modifications to Improve 5-HMT Delivery..... | 17 |
| C. | Berge and Johansson Taught Fumarate Salts..... | 20 |
| VIII. | DETAILED GROUNDS FOR UNPATENTABILITY..... | 21 |
| A. | Claims 1-5 are Obvious Over the Postlind and Bundgaard Publications in view of the Detrol® Label and Berge..... | 21 |
| 1. | A Person of Ordinary Skill Would Have Been Motivated to Look at Improved 5-HMT Administration in View of Tolterodine..... | 22 |
| 2. | Postlind and Bundgaard Publications in View of the Detrol® Label and Berge Would Have Led to Prodrug Optimization and Fumarate Salt Forms..... | 25 |
| 3. | Summary of Proposed Rejection of Claims 1-5..... | 31 |
| B. | Claims 21-24 are Obvious over the Postlind and Bundgaard Publications in view of the Detrol® Label and Berge..... | 40 |
| C. | Claims 1-5 and 21-24 Are Rendered Obvious by Brynne 1998, Bundgaard, and Johansson..... | 44 |
| 1. | A Person of Ordinary Skill Would Have Been Motivated to Look at Improved 5-HMT Administration in View of Tolterodine..... | 44 |
| 2. | Brynne 1998 in View of Bundgaard and Johansson Would Have Led to Prodrug Optimization and Fumarate Salt Forms..... | 45 |
| IX. | EVEN IF CONSIDERED, SECONDARY CONSIDERATIONS FAIL TO OVERCOME THE EVIDENCE OF OBVIOUSNESS..... | 53 |
| X. | THE PROPOSED REJECTIONS RAISE NEW ISSUES IN WHICH PETITIONER WILL LIKELY PREVAIL..... | 58 |

TABLE OF AUTHORITIES

| | Page(s) |
|--|----------------|
| FEDERAL CASES | |
| <i>In re Applied Materials</i> , 692 F.3d 1289 (Fed. Cir. 2012) | 32 |
| <i>Bristol-Myers Squibb Co. v. Teva Pharm. USA Inc.</i> , 752 F.3d 967 (Fed. Cir. 2014) | 56, 57 |
| <i>Daiichi Sankyo Co. v. Matrix Labs., Ltd.</i> , 619 F.3d 1346 (Fed. Cir. 2010) | 13, 14, 23, 32 |
| <i>In re Dillon</i> , 919 F.2d 688 (Fed. Cir. 1990) | 13 |
| <i>Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.</i> , 471 F.3d 1369 (Fed. Cir. 2006) | 32 |
| <i>Geo M. Martin Co. v. All. Machine Sys. Int’l LLC</i> , 618 F.3d 1294 (Fed. Cir. 2010) | 55 |
| <i>In re Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011) | 54, 58 |
| <i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)..... | 13, 32 |
| <i>McNeil-PPC, Inc. v. L. Perrigo Co.</i> , 337 F.3d 1362 (Fed. Cir. 2003) | 55 |
| <i>Merck & Co. v. Teva Pharms. USA, Inc.</i> , 395 F.3d 1364 (Fed. Cir. 2005) | 15 |
| <i>Ormco Corp. v. Align Tech., Inc.</i> , 463 F.3d 1299 (Fed. Cir. 2006) | 54 |
| <i>Par Pharm., Inc. v. TWI Pharms., Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014) | 14 |
| <i>Pfizer Inc. and UCB Pharma GMBH v. Mylan Pharmaceuticals Inc.</i> , No. 1:15-cv-00013-IMK (N.D. W. Va.)..... | 1 |

Pfizer, Inc. and UCB Pharma GMBH v. Mylan Pharmaceuticals, Inc.,
No. 1:15-cv-00079-GMS (D. Del.).....1, 21, 30

Pfizer, Inc. and UCB Pharma GMBH v. Sandoz, Inc., et al.,
No. 1:13-cv-01110-GMS (D. Del.).....1

Pfizer, Inc. v. Apotex, Inc.,
480 F.3d 1348 (Fed. Cir. 2007)21, 30, 31, 54

Tex. Instruments v. U.S. Int’l Trade Comms’n,
988 F.2d 1165 (Fed. Cir. 1993)57

FEDERAL STATUTES

35 U.S.C. §§ 102(a)-(b)4

35 U.S.C. § 10358

35 U.S.C. § 3113

35 U.S.C. § 312(a)(1).....2

35 U.S.C. § 314(a)58

35 U.S.C. §§ 3151

REGULATIONS

37 C.F.R. § 42.10(b)2

37 C.F.R. § 42.152

37 C.F.R. § 42.100(b)6

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.