Trials@uspto.gov
571.272.7822

Paper No. 12
Entered: July 20, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
and MYLAN LABORATORIES LIMITED,
Petitioner,

v.

UCB PHARMA GMBH,
Patent Owner.

Case IPR2016-00517
Patent 7,985,772 B2

Before RAMA G. ELLURU, KRISTINA M. KALAN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited, ("Mylan" or "Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1, 3, 4, and 6–8 of U.S. Patent No. 7,985,772 B2 (Ex. 1001, "the '772 patent"). Paper 5 ("Pet."). UCB Pharma GmbH, ("UCB" or "Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1, 3, 4, and 6–8. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Patent Owner asserts that

> UCB and Pfizer Inc. ("Pfizer"), the exclusive licensee of the '772 patent, have sued Mylan Pharmaceuticals Inc. for infringement of the '772 patent in the following actions: *Pfizer, Inc. and UCB Pharma GMBH v. Mylan Pharmaceuticals, Inc.*, No. 1:15-cv-00079-GMS (D. Del.) and *Pfizer Inc. and UCB Pharma GMBH v. Mylan Pharmaceuticals Inc*., Case No. 1:15-cv-00013-IMK (N.D.W.Va.).

Paper 8, 2; *see* Pet. 1–2 (noting that Pfizer is the NDA filer).

The '772 patent is also at issue in *Pfizer, Inc. v. Sandoz, Inc.*, No. 1:13-cv-01110-GMS (D. Del.),[1] and in the now-dismissed action, *Pfizer, Inc.*

[1] Patent Owner provides, as Exhibit 2001, the District Court's Memorandum finding that the defendants in that proceeding "failed to

v. Dr. Reddy's Laboratories, Ltd., No. 1:15-cv-01067 (GMS) (D. Del.). Paper 8, 2; Prelim. Resp. 7–8.

In addition to the case before us, Petitioner requested institution of *inter partes* review in the following matters involving patents with substantially the same specification as the '772 patent at issue here:

Case No. IPR2016-00512 (U.S. Patent No. 7,384,980 B2);

Case No. IPR2016-00514 (U.S. Patent No. 7,855,230 B2); and

Case No. IPR2016-00516 (U.S. Patent No. 8,338,478 B2).

Petitioner also requested institution of *inter partes* review in IPR2016-00510 (U.S. Patent No. 6,858,650 B1), a matter involving another UCB patent generally directed, as are the above patents, to 3,3-diphenylpropylamine compounds.

B. The '772 Patent

The '772 patent, entitled "Derivatives of 3,3-Diphenylpropylamines," issued on July 26, 2011, with Claus Meese and Bengt Sparf as the listed co-inventors. Ex. 1001. The '772 patent is generally directed to "derivatives of 3,3-diphenylpropylamines, methods for their preparation, pharmaceutical compositions containing the novel compounds, and the use of the compounds for preparing drugs." Ex. 1001, Abstract.

The Specification discloses that "normal urinary bladder contractions are mediated mainly through cholinergic muscarinic receptor stimulation."

---

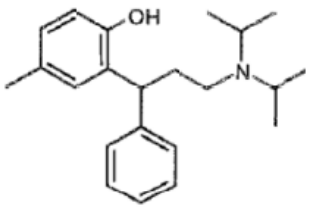
present a prima facie case that the asserted claims of the patents-in-suit are invalid as obvious." Ex. 2001, 19; *see* Prelim. Resp. 7–8. Although the district court reached this determination on a different record and applying different standards, the arguments and references applied overlap with those before us. *See* Ex. 2001, Prelim. Resp. 1–2, 15–17, 21, 25, 33. Accordingly, while we are not bound to these findings, we find the court's analysis informative.

Id. at 1:23–24. Because the same muscarinic receptors appear to also mediate contractions of the overactive bladder and associated symptoms of urinary frequency, frequency urge, and urge incontinence, antimuscarinic drugs have been proposed for the treatment of bladder overactivity. *Id.* at 1:25–30. "Among the antimuscarinic drugs available on the market, oxybutynin is currently regarded as the gold standard for pharmacological treatment of urge incontinence and other symptoms related to bladder overactivity" but its usefulness is limited by antimuscarinic side effects, most particularly, dry mouth. *Id.* at 1:31–34.

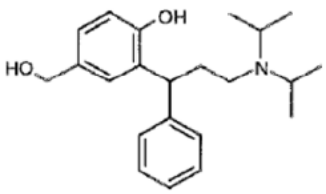
"Tolterodine is a new, potent and competitive, muscarinic receptor antagonist intended for the treatment of urinary urge incontinence and [bladder wall muscle] hyperactivity. Preclinical pharmacological data show that tolterodine exhibits a favourable tissue selectivity in vivo for the urinary bladder over the effect on the salivation" as compared to oxybutynin. *Id.* at 1:42–48.

A major metabolite of tolterodine, the 5-hydroxymethyl derivative 5-HMT ("5-HMT"), shows in vitro and in vivo pharmacological profiles almost identical to those of tolterodine. *Id.* at 55–59 (citing Nilvebrant et al., 1997, Eur. J. Pharmacol. 327 (1997), 195–207). "WO 94/1 1337 proposes [5-HMT] as a new drug for urge incontinence." *Id.* at 1:63–64.

The chemical structures of tolterodine and its active metabolite, 5-HMT (indicated below by "5-HM"), are shown below:



Tolterodine

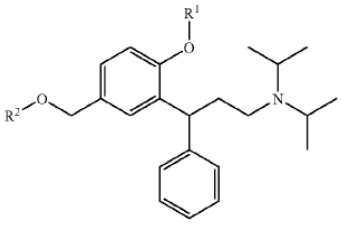


5-HM

See, e.g., Pet. 19; Ex. 1010, 289; Ex. 1011, 530. As illustrated above, tolterodine has a single hydroxyl group at the 2-position of the methylated phenolic ring, whereas 5-HMT bears a second hydroxyl moiety on the 5-position methyl group of that ring.

C. Challenged Claims

Claim 1 recites:

> 1. 3,3-Diphenylpropylamines of the general formula
>
> 
>
> wherein:
>
> R^1 is a hydrogen and R^2 is C_1-C_6 alkylcarbonyl; or
>
> R^1 is C_1-C_6 alkylcarbonyl and R^2 is hydrogen;
>
> their salts with physiologically acceptable acids, their free bases and, when the 3,3-Diphenylpropylamines are in the form of optical isomers, the racemic mixture and the individual enantiomers.

Claim 2 specifies that R^1 is a hydrogen and R^2 is C_1-C_6 alkylcarbonyl; claims 4, 6, and 7 recite methods of treating urinary incontinence using the compounds of claims 1 and 2; and claim 8 recites a pharmaceutical composition comprising those compounds and a pharmaceutically acceptable carrier.

The compositions of claims 1 and 2 encompass fesoterodine fumarate (R-(+)-2-(3-(diisopropylamino-1-phenylpropyl)-4-hydroxymethl-phenylisobutyrate ester hydrogen fumarate) distributed by Pfizer Labs under the tradename TOVIAZ. *See* Pet. 6; Prelim. Resp. 1–2, 7; Ex. 1024, 8, 19.

DOCKET ALARM

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.