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Paper 37
Entered: July 19, 2017

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 KRISTINA M. KALAN, ROBERT A. POLLOCK, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

FINAL WRITTEN DECISION

Finding Claims 1, 3, 4, and 6–8 Not Unpatentable
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

Dismissing as Moot Patent Owner's Motion to Exclude
37 C.F.R. § 42.64(c)

Granting Joint Motion to Seal and Entering Default Protective Order
37 C.F.R. § 42.54

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 instituted an *inter partes* review of claims 1, 3, 4, and 6–8 on the grounds of unpatentability alleged in the Petition. Paper 12 ("Inst. Dec."). After institution of trial, Patent Owner filed a Patent Owner Response (Paper 17, "PO Resp.") and Petitioner filed a Reply (Paper 21, "Reply"). An oral hearing was held on April 5, 2017. A transcript of the hearing has been entered into the record. Paper 36 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6. In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 3, 4, and 6–8 of the '772 patent are unpatentable under 35 U.S.C. § 103.

II. BACKGROUND

A. Related Matters

Patent Owner asserts that

> UCB and Pfizer Inc. ("Pfizer"), the exclusive licensees 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 holder).

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

In addition to the case before us, we instituted *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).

We also instituted *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.[2]

Patent Owner updated its mandatory notices on February 16, 2017, to reflect that Case No. 1:15-cv-00079-GMS concluded with a general verdict in favor of Plaintiffs, and that UCB Pharma GmbH and Pfizer Inc., the exclusive licensee of the asserted patents, filed suit against Torrent Pharmaceuticals Limited and Torrent Pharma Incorporated for infringement

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[1] Patent Owner provides, as Exhibit 2001, the District Court's Memorandum finding that the defendants in that proceeding "failed to present a prima facie case that the asserted claims of the patents-in-suit are invalid as obvious." Ex. 2001, 19. Although the district court reached this determination on a different record and applied different standards, the arguments and references applied overlap with those before us. *See* Ex. 2001. Accordingly, while we are not bound to these findings, we find the court's analysis informative.

[2] Petitioners Alembic Pharmaceuticals Limited from IPR2016-01596, Torrent Pharmaceuticals Limited from IPR2016-01636, and Amerigen Pharmaceuticals Limited from IPR2016-01665 were joined as Petitioners to IPR2016-00510. IPR 2016-00510, Papers 24–26.

of the asserted patents in *Pfizer, Inc. and UCB Pharma GmbH v. Torrent Pharm. Ltd.*, No. 1:17-cv-00112-GMS (D. Del.). Paper 26, 2.

B. The '772 Patent

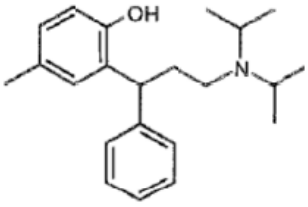
The '772 patent, entitled "Derivatives of 3,3-Diphenylpropylamines," issued on July 26, 2011, with Claus Meese and Bengt Sparf as the listed co-inventors. Ex. 1001. The '772 patent is generally directed to "derivatives of 3,3-diphenylpropylamines, methods for their preparation, pharmaceutical compositions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

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

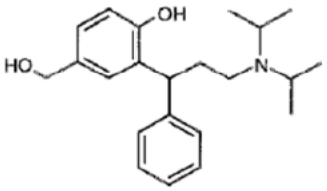
"Tolterodine is a new, potent and competitive, muscarinic receptor antagonist intended for the treatment of urinary urge incontinence and [bladder wall muscle] hyperactivity. Preclinical pharmacological data show that tolterodine exhibits a favourable tissue selectivity in vivo for the urinary bladder 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 1:55–59 (citing Nilvebrant et al., 1997, Eur. J. Pharmacol. 327 (1997), 195–207). "WO 94/11337 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



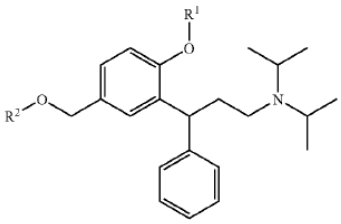
5-HM

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

C. Illustrative Claim

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;

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