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 IPR2016-00510
Patent 6,858,650 B1

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

ANKENBRAND, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited, (collectively, "Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–5 and 21–24 of U.S. Patent No. 6,858,650 B1 (Ex. 1001, "the '650 patent"). Paper 5 ("Pet."). UCB Pharma GmbH, ("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." Applying that standard, and upon considering the information presented in the Petition and the Preliminary Response, we institute an *inter partes* review of claims 1–5 and 21–24.

A. Related Proceedings

Patent Owner asserts that

> [Patent Owner] and Pfizer Inc. ("Pfizer"), the exclusive licensee of the '650 patent, have sued Mylan Pharmaceuticals Inc. for infringement of the '650 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 7, 2; *see* Pet. 1–2 (noting that Pfizer is the NDA filer).

The '650 patent also is asserted in *Pfizer, Inc. v. Sandoz, Inc.*, No. 1:13-cv-01110-GMS (D. Del.),[1] and was asserted in the now-dismissed

[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; *see* Prelim. Resp. 7–8. The district court

action, *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.*, No. 1:15-cv-01067-GMS (D. Del.). Paper 7, 2.

In addition to the case before us, Petitioner requested institution of *inter partes* review in the following matters involving patents generally directed to 3,3-diphenylpropylamine compounds: Case No. IPR2016-00512 (U.S. Patent No. 7,384,980 B2); Case No. IPR2016-00514 (U.S. Patent No. 7,855,230 B2); Case No. IPR2016-00516 (U.S. Patent No. 8,338,478 B2), and Case No. IPR2016-00517 (U.S. Patent No. 7,985,772 B2).

B. The '650 Patent

The '650 patent, titled "Stable salts of novel derivatives of 3,3-diphenylpropylamines," issued on February 22, 2005. Ex. 1001. The '650 patent is generally directed to "highly pure, crystalline stable compounds of novel derivatives of 3,3-diphenylpropylamines in the form of their salts, a method for the[ir] manufacture and highly pure, stable intermediate products." *Id.* at Abstract, 1:10–14.

The specification discloses that the compounds "are valuable prodrug[s] for the treatment of urinary incontinence and other spasmodic complaints" that "overcome the disadvantage[s] of the active substances available to date." *Id.* at 1:17–20. Those disadvantages include "inadequate absorption of the active substance by biological membranes or the unfavourable metabolism of [the active substance]." *Id.* at 1:20–22. According to the specification, the compounds also "have improved

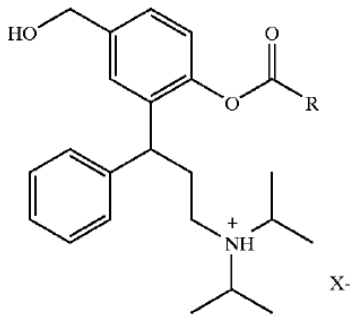
---

reached that determination on a different record and applying different standards, but the arguments and references applied overlap with those before us. *See* Ex. 2001; Prelim. Resp. 1–2, 15–17, 21, 25, 33. Accordingly, although we are not bound by those findings, we find the district court's analysis informative.

pharmacokinetic characteristics compared with Oxybutynin and Tolterodin[e]," two muscarinic receptor antagonists used to treat patients with overactive bladder. *Id.* at 1:23–25; Ex. 1009, 3; Ex. 1014, 528.

C. Illustrative Claim

Of the challenged claims, claim 1 is independent and recites:

> 1. Compounds of general formula I
>
> Formula I
>
> 
>
>
> in which R denotes C_1–C_6-alkyl, C_3–C_{10}-cycloalkyl, substituted or unsubstituted phenyl and X^- is the acid residue of a physiologically compatible inorganic or organic acid.

Id. at 23:15–32.

Claims 2 and 3 narrow claim 1 by specifying that X^- is an acid ester chosen from an enumerated list of acids, including fumaric acid, and requiring that the compounds have specific chirality (i.e., the (R) enantiomer), respectively. *Id.* at 23:33–65. Claims 4 and 5 depend from claim 3 and, therefore, inherit the chirality limitation of claim 3. Like claim 2, claim 4 specifies that X^- is an acid ester chosen from an enumerated list of acids, including fumaric acid. *Id.* at 23:66–24:13. Claim 5 further narrows the compounds to the fumarate or hydrochloride salts. *Id.* at 24:14–19. Claims 21–23 recite methods of treating urinary incontinence disorder using the compounds of claims 1, 3, and 5, respectively. *Id.* at 30:30–41. Claim

24 recites the method of any one of claims 21–23 and limits the urinary incontinence disorder to urge incontinence. *Id.* at 30:42–43.

The compositions of claims 1–5 encompass fesoterodine fumarate (R-(+)-2-(3-(diisopropylamino-1-phenylpropyl)-4-hydroxymethl-phenylisobutyrate ester hydrogen fumarate)) distributed by Pfizer Labs under the brand TOVIAZ. *See* Pet. 5; Prelim. Resp. 1–2, 7; Ex. 1024, 8, 19.

D. The Asserted Grounds of Unpatentability

The Petition asserts the following grounds of unpatentability:

References	Basis	Claims Challenged
Postlind,[2] "Bundgaard publications,"[3,4,5] Detrol Label,[6] and Berge[7]	§ 103	1–5 and 21–24
Brynne,[8] Bundgaard publications, and Johansson[9]	§ 103	1–5 and 21–24

[2] Postlind et al., *Tolterodine, A New Muscarinic Receptor Antagonist, is Metabolized by Cytochromes P450 2D6 and 3A in Human Liver Microsomes*, 26(4) DRUG METABOLISM & DISPOSITION 289–293 (1998) (Ex. 1010) ("Postlind").

[3] We interpret Petitioner's reference to "Bundgaard publications" as referring to Exhibits 1012 and 1020. *See* Pet. iv, 3, 19–20, 27, 29.

[4] Bundgaard, Design of Prodrugs Elsevier (1985) (Ex. 1012) ("Bundgaard").

[5] WO 92/08459, published May 29, 1992 (Ex. 1020) ("Bundgaard PCT").

[6] Detrol™ (tolterodine tartrate tablets) prescribing information (1998) (Ex. 1009) ("Detrol Label").

[7] Berge et al., *Pharmaceutical Salts*, 66(1) J. PHARM. SCI. 1–19 (1977) (Ex. 1013) ("Berge").

[8] Brynne et al., *Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine*, 63(5) CLIN. PHARMACOL. & THERAPEUTICS 529–539 (1998) (Ex. 1011) ("Brynne").

[9] Johansson et al., WO 94/11337, published May 26, 1994 (Ex. 1005) ("Johansson").

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.