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Paper No. 45
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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[1]
Patent 6,858,650 B1

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

ANKENBRAND, *Administrative Patent Judge.*

FINAL WRITTEN DECISION

Finding Claims 1–5 and 21–24 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

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[1] Petitioners Alembic Pharmaceuticals Limited from IPR2016-01596, Torrent Pharmaceuticals Limited from IPR2016-01636, and Amerigen Pharmaceuticals Limited from IPR2016-01665 have been joined as Petitioners to this proceeding.

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–5 and 21–24 (collectively, "the challenged claims") of U.S. Patent No. 6,858,650 B1 (Ex. 1001, "the '650 patent"). We have jurisdiction under 35 U.S.C. § 6. For the reasons that follow, we determine that Petitioner does not demonstrate, by a preponderance of the evidence, that claims 1–5 and 21–24 are unpatentable.

A. Procedural History

Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited ("Mylan") filed a Corrected Petition (Paper 5, "Pet.") requesting an *inter partes* review pursuant to 35 U.S.C. § 311.[2] On July 20, 2016, we instituted trial to determine (1) whether claims 1–5 and 21–24 are unpatentable under 35 U.S.C. § 103(a) over the combination of Postlind,[3] "Bundgaard

[2] In support of the Corrected Petition, Petitioner filed the declaration of its technical expert, Steven E. Patterson, Ph.D. (Ex. 1003), and the declaration of DeForest McDuff, Ph.D. (Ex. 1033) with respect to lack of commercial success.

[3] 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).

publications,"[4,5,6] Detrol Label,[7] and Berge;[8] and (2) whether claims 1–5 and 21–24 are unpatentable under 35 U.S.C. § 103(a) over the combination of Brynne,[9] Bundgaard publications, and Johansson.[10] Paper 12 ("Institution Decision" or "Inst. Dec.").

After the Institution Decision, Alembic Pharmaceuticals Limited ("Alembic"), Torrent Pharmaceuticals Limited ("Torrent"), and Amerigen Pharmaceuticals Limited ("Amerigen") were each joined as petitioners to the proceeding. *See* Case IPR2016-01596, Paper 8; Case IPR2016-01636, Paper 10; Case IPR2016-01665, Paper 8. Accordingly, we refer to Mylan, Alembic, Torrent, and Amerigen collectively as "Petitioner."

During trial, UCB Pharma GmbH ("Patent Owner") filed a Response (Paper 20, "Resp."),[11] and Petitioner filed a Corrected Reply (Paper 28, "Reply"). Patent Owner filed a Motion to Exclude, which is fully briefed.

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[4] In the Institution Decision, we interpreted Petitioner's reference to "Bundgaard publications" as referring to Exhibits 1012 and 1020. Inst. Dec. 5 n.3. We discuss those Exhibits individually in our analysis herein, and also reference the Bundgaard publications collectively.
[5] Bundgaard, Design of Prodrugs, Elsevier (1985) (Ex. 1012, "Bundgaard").
[6] WO 92/08459, published May 29, 1992 (Ex. 1020, "Bundgaard PCT").
[7] Detrol™ (tolterodine tartrate tablets) prescribing information (1998) (Ex. 1009).
[8] Berge et al., *Pharmaceutical Salts*, 66(1) J. PHARM. SCI. 1–19 (1977) (Ex. 1013).
[9] Brynne et al., *Influence of CYP2D6 polymorphism on the pharmacokinetics and pharmacodynamics of tolterodine*, 63(5) CLIN. PHARMACOL. & THERAPEUTICS 529–539 (1998) (Ex. 1011).
[10] WO 94/11337, published May 26, 1994 (Ex. 1005).
[11] With the Response, Patent Owner filed the declarations of Hans Maag, Sc.D. (Ex. 2021), William R. Roush, Ph.D. (Ex. 2022), Scott A. MacDiarmid, M.D., FRCPSC (Ex. 2023), Leonard J. Chyall, Ph.D. (Ex. 2024), and Claus O. Meese, Ph.D. (Ex. 2025).

Paper 37 (Motion); Paper 39 (Response); Paper 40 (Reply). The parties also filed a Joint Motion to Seal and for Entry of a Protective Order. Paper 34. The record further includes a transcript of the final oral hearing conducted on April 5, 2017. Paper 43 ("Tr.").

B. 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.),[12] and was asserted in the now-dismissed 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, we instituted an *inter partes* review in the following matters involving patents generally directed to 3,3-diphenylpropylamine compounds: Case IPR2016-00512 (U.S. Patent No. 7,384,980 B2) ("the '980 patent"); Case IPR2016-00514 (U.S. Patent

[12] 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. The district court reached that determination on a different record and applied different standards, but the arguments and references applied overlap with those before us. *See* Ex. 2001. Accordingly, although we are not bound by those findings, we find the district court's analysis informative.

No. 7,855,230 B2); Case IPR2016-00516 (U.S. Patent No. 8,338,478 B2), and Case IPR2016-00517 (U.S. Patent No. 7,985,772 B2).

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 Patent Owner and Pfizer filed suit against Torrent and Torrent Pharma Incorporated for infringement of the '650 patent, as well as the patents challenged in Case IPR2016-00512, Case IPR2016-00514, Case IPR2016-00516, and Case IPR2016-00517. Paper 33, 2. That action is captioned *Pfizer, Inc. v. Torrent Pharm. Ltd.*, No. 1:17-cv-00112-GMS (D. Del.). *Id.*

C. 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 generally is 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 unfavoura[b]le metabolism of [the active substance]." *Id.* at 1:20–22. According to the specification, the compounds also "have improved pharmacokinetic characteristics compared with Oxybutynin and

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