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Paper No. 18
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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
Patent 6,858,650 B1

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

ANKENBRAND, *Administrative Patent Judge*.

DECISION
Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

On August 3, 2016, Patent Owner filed a Request for Rehearing (Paper 15, "Rehearing Request" or "Reh'g Req.") of our Decision instituting an *inter partes* review (Paper 12, "Decision" or "Dec.") of U.S. Patent No. 6,858,650 B1 (Ex. 1001, "the '650 patent"). The asserted grounds on which we instituted an *inter partes* review are listed in the following table:

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

Patent Owner requests rehearing on both grounds (Ground I and Ground II), but only as to claims 5 and 23. For the reasons discussed below, we grant Patent Owner's Request for Rehearing and reconsider the record evidence regarding the identification of the 5-hydroxymethyl derivative of tolterodine ("5-HMT"). We modify our analysis in determining that

[1] 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").
[2] Bundgaard, *Design of Prodrugs*, Elsevier (1985) (Ex. 1012) ("Bundgaard").
[3] WO 92/08459, published May 29, 1992 (Ex. 1020) ("Bundgaard PCT").
[4] Detrol™ (tolterodine tartrate tablets) prescribing information (1998) (Ex. 1009) ("Detrol Label").
[5] Berge et al., *Pharmaceutical Salts*, 66(1) J. PHARM. SCI. 1–19 (1977) (Ex. 1013) ("Berge").
[6] 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").
[7] Johansson et al., WO 94/11337, published May 26, 1994 (Ex. 1005) ("Johansson").

Petitioner has demonstrated a reasonable likelihood that one of ordinary skill in the art would have selected 5-HMT over tolterodine for further development. We deny the Rehearing Request in all other respects.

ANALYSIS

When considering a request for rehearing, the Board reviews its decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The party requesting rehearing bears the burden of showing that the decision should be modified, and "[t]he request must specifically identify all matters the party believes the Board misapprehended or overlooked." 37 C.F.R. § 42.71(d).

Patent Owner asserts that our Decision misquotes and misapplies 37 C.F.R. § 42.108(c) in determining that Petitioner demonstrated a reasonable likelihood that one of ordinary skill in the art would have selected 5-HMT over tolterodine by viewing all supporting evidence, rather than only testimonial evidence, in the light most favorable to Petitioner. Reh'g Req. 4–8. Patent Owner also asserts that our factual findings regarding the selection of a monoester at the 2 position of 5-HMT and the method of treatment claims are unsupported by substantial evidence. *Id.* at 8–15. We address each of those assertions below.

A. Application of 37 C.F.R. § 42.108(c)

Patent Owner argues that our Decision misquotes and misapplies 37 C.F.R. § 42.108(c) by viewing all supporting evidence, rather than only testimonial evidence, in the light most favorable to Petitioner, at least in connection with the "identification of 5-HMT" portion of the obviousness analysis. Reh'g Req. 4–8. We acknowledge that 37 C.F.R. § 42.108(c) provides that "a genuine issue of material fact created by . . . testimonial evidence will be viewed in the light most favorable to the petitioner solely

for the purposes of deciding whether to institute an *inter partes* review." As a result, we have reconsidered the evidence and arguments presented in the Petition and Preliminary Response. Upon reconsidering the record, as developed at the preliminary stage of this proceeding, we remain of the opinion that Patent Owner's arguments and supporting evidence create factual issues that are best resolved at trial, with the benefit of a full record.[8] We, therefore, maintain our determination that Petitioner has demonstrated a reasonable likelihood that the ordinarily skilled artisan would have selected 5-HMT over tolterodine for further development, as well as a reasonable likelihood that the ordinarily skilled artisan would have selected the remaining steps proposed by the Petitioner, which we analyzed under 37 C.F.R. § 42.108(c).

B. The Board's Factual Findings

Patent Owner asserts that our factual findings regarding the selection of a monoester at the 2 position of 5-HMT and regarding the method of treatment claims are unsupported by substantial evidence. *Id.* at 8–15. Patent Owner repeats in the Rehearing Request essentially the same arguments raised in the Preliminary Response, e.g., the argument that Dr. Patterson's testimony is not supported by any prior art. *Compare* Prelim. Resp. 28, *with* Reh'g Req. 9–10. Patent Owner's disagreement with

[8] As we explained in the Decision, our determinations at the institution stage are preliminary in nature and may be revisited during trial when the record is fully developed. Dec. 28. Patent Owner, therefore, may continue to press its argument regarding identification of 5-HMT over tolterodine (and its arguments regarding the remaining steps) for further development in the Patent Owner Response.

our assessment of presented arguments and evidence, however, is not a proper basis for rehearing.

Patent Owner also contends that we disregarded an argument regarding Petitioner's showing as to Ground II of method claim 23. Reh'g Req. 14–15. As an initial matter, it is not clear from the Rehearing Request whether Patent Owner's argument is directed to using a fumarate salt of fesoterodine to treat urinary incontinence, or to making a salt (e.g., a fumarate salt) of fesoterodine. To the extent that Patent Owner's argument is directed to the former, we did not disregard that argument. Rather, in the Decision, we were persuaded by Petitioner's argument and evidence that the ordinarily skilled artisan "would have expected the use of the compound in claim 1 to be quickly metabolized to the active compound, 5-HMT, which was well known to be beneficial for the treatment of urinary incontinence." Dec. 25 (quoting Pet. 39).

To the extent that Patent Owner's argument is directed to making a fesoterodine salt, we also did not disregard that argument. To the contrary, we found persuasive Petitioner's argument, as supported by Dr. Patterson's testimony, that "once the esterified prodrug was made, the selection of [a] salt[] would have been a matter of routine experimentation." *Id.* at 23–24 (citing Pet. 20–21; Ex. 1003 ¶ 131); *see* Ex. 1003 ¶ 131 (citing Ex. 1013 (Berge) for the proposition that "salt formation is a matter of routine experimentation"); Ex. 1013, 1 ("The chemical, biological, physical, and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form."). In any event, as we explained in the Decision, Patent Owner's arguments and supporting

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