UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.
_____

Case IPR2016-00627
Patent 5,847,170

_____

Before BRIAN P. MURPHY, TINA E. HULSE, and CHRISTOPHER M.
KAISER, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I.   INTRODUCTION

Mylan Laboratories Limited ("Petitioner") filed a Request for Rehearing following our Decision Denying Institution of the Petition challenging the patentability of claims 1 and 2 in U.S. Patent No. 5,847,170 (Ex. 1001, "the '170 patent"). Paper 10 ("Decision" or "Dec."); Paper 11 ("Rehearing Request" or "Req. Reh'g"). Having considered Petitioner's Rehearing Request, it is *denied*.

II.   STANDARD OF REVIEW

A party who requests rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters we misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id*. When rehearing a decision on petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). "A Request for Rehearing is not an opportunity to re-argue old arguments." *Histologics, LLC v. CDX Diagnostics, Inc. et al.*, Case IPR2014-00779, slip op. at 4 (PTAB Oct. 16, 2014) (Paper 9). Petitioner's Rehearing Request amounts to a re-argument of the contentions raised in the Petition and rejected by the Board. We briefly address Petitioner's rehearing contentions below.

III.   DISCUSSION

A. *Asserted Errors of Law*

Petitioner argues that the Board's Decision applied "erroneous legal standards" in four different ways. Req. Reh'g 3–9.

Petitioner first contends that our Decision improperly required "that Kant alone provide motivation to modify Compound 20 in order to select it as a lead compound." Req. Reh'g 4–5. Our Decision cited and applied the law that governs Petitioner's lead compound theory. Dec. 11 (citing *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1291–92 (Fed. Cir. 2012); *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010) ("[T]he attribution of a compound as a lead compound after the fact *must avoid hindsight bias*; it must look at the state of the art at the time the invention was made to find *a motivation to select and then modify* a lead compound to arrive at the claimed invention.") (emphases added); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007)). In particular, *Daiichi Sankyo* provides that a patent challenger must first establish a motivation for a person of ordinary skill in the art ("POSA") "to select" a lead compound without hindsight bias, an issue addressed at length in our Decision. Dec. 12–14. The motivation to select a lead compound for further modification must be supported with persuasive evidence, whether it be the teachings of the Kant reference, the Klein reference, the knowledge of a POSA reflected in other prior art references, expert testimony, or some combination thereof. We did not "require" a motivation be found in Kant alone. *Id.* Petitioner misconstrues our Decision

and the law, focusing on selective snippets of our analysis while ignoring others and the evidence on which we relied for our determination.

With regard to finding a motivation "to modify" a lead compound, once selected, we considered multiple factors regarding Petitioner's assertion that a POSA "would have modified Kant Compound 20 in view of Klein's Table III (compounds 8 and 10)." Dec. 11, 14–17. We provided a substantive discussion and analysis, and included extensive citations to the Petition and prior art Klein reference, in support of our determination that "Petitioner's rationale and supporting evidence that a POSA would have modified Kant Compound 20 in view of Klein to make the required substitutions at C-7 and C-10 to synthesize cabazitaxel" was unpersuasive. Dec. 14–17. We see no reason to reconsider our analysis and determination regarding a motivation to select and modify a lead compound.

Petitioner next asserts we confused a synthetic precursor, 10-DAB, with a lead compound. Req. Reh'g 5–6. To the contrary, we clearly indicated that Kant used 10-DAB as a starting material "for synthesizing analogues of paclitaxel with the 'aim of obtaining drugs having more desirable properties,'" such as Kant Compound 20. Dec. 7 (citing Ex. 1005, 5543 ¶¶ 2–3). In addition, rather than "misapprehend[] that Kant studied compounds with the paclitaxel and the docetaxel side chains," as argued by Petitioner (Req. Reh'g 5), we explicitly acknowledged and discussed the point. *Id.* at 5–8, 12.

Petitioner next asserts that we "erroneously requir[ed] superiority [of Kant Compound 20] over docetaxel" and overlooked Petitioner's reliance on Table II of Kant. Req. Reh'g 7–8. We did not "require" such superiority. Rather, we noted that Kant did not provide any comparative performance

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data with respect to docetaxel, which, unlike paclitaxel, contains the same side chain as Compound 20. Dec. 12. We did not overlook Petitioner's reliance on Kant Table II. We explained, annotated, and reproduced Kant Table II in our Decision, and we cited it in our analysis. Dec. 7–8, 12. Petitioner's assertions are nothing more than re-arguments of those we considered and rejected in our Decision.

Petitioner's fourth contention of legal error, for "misattributing *Graham* factor 3 analysis as improper hindsight," is based on the curious argument that "nowhere does the Petition argue that Compound 20 should be selected as a lead because of its structural similarity to cabazitaxel." Req. Reh'g 8–9. Yet, the Petition begins, ends, and overflows with characterizations of cabazitaxel as 7,10-dimethoxy *docetaxel*, and repeatedly points to the structural similarities between docetaxel, Kant Compound 20, and 7,10-dimethoxy docetaxel (cabazitaxel) as the basis for selecting Kant Compound 20 as a lead compound for further modification in view of Klein. *See* Pet. 1–2 ("the only difference between the two [Kant Cpd 20 and cabazitaxel] is the methyl group on the C-7 hydroxyl"), 6–7 ("Kant discloses 10-methoxy docetaxel (compound 20), which contains the same methoxy group at the C-10 position as 7,10-dimethoxy docetaxel. . . . Compound 20, which is methylated at the C-10 hydroxyl is shown below on the left, adjacent to 7,10-dimethoxy docetaxel for comparison [of the chemical structures]"), 30–31 ("The structure disclosed in Kant [Compound 20] is shown below, adjacent to the compound of claim 1 of the '170 patent and adjacent to docetaxel. For ease of comparison, the identical portions of the molecules have been depicted in grey."). We reiterate our determination that Petitioner "errs by starting with a hindsight-biased structural comparison of

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