

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LOWER DRUG PRICES FOR CONSUMERS, LLC,
Petitioner,

v.

FOREST LABORATORIES HOLDINGS LIMITED,
Patent Owner.

Case IPR2016-00379
Patent 6,545,040 B1

Before MICHAEL P. TIERNEY, LORA M. GREEN, and
TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

DECISION
Denying Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Lower Drug Prices for Consumers, LLC (“Petitioner”) filed a Request for Rehearing (Paper 15, “Reh’g Req.”) of our Decision (Paper 14, “Dec.”) denying institution of an *inter partes* review of claims 1–6 of U.S. Patent No. 6,545,040 B1 (Ex. 1001, “the ’040 patent”).

In our Decision, we concluded that substantially the same prior art and substantially the same arguments were presented to the Office previously. We, therefore, exercised our discretion to deny the Petition under 35 U.S.C. § 325(d). Petitioner requests a rehearing of our decision, arguing that we erred in deferring to the Board’s prior allowance of the ’040 patent. Reh’g Req. 2.

For the reasons stated below, Petitioner’s request is *denied*.

II. STANDARD OF REVIEW

Under 37 C.F.R. § 42.71(c), “[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion.” An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus., Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988). The request must identify, specifically, all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply. 37 C.F.R. § 42.71(d).

III. ANALYSIS

As an initial matter, we note that, aside from a conclusory statement stating otherwise (Reh’g Req. 4), Petitioner does not argue that we erred in determining that the Petition presents substantially the same prior art as was

previously presented to the Office. Nor could it in light of the fact that Petitioner relies primarily on the same prior art that the examiner relied on during examination. *See* Dec. 9 (noting Petitioner and examiner both relied on Van Lommen¹). Because, under 35 U.S.C. § 325(d), we have discretion to reject a Petition if “the same or substantially the same prior art *or* arguments previously were presented to the Office,” Petitioner has not established that we abused our discretion in denying the Petition because substantially the same prior art was previously before the Office. *See* § 325(d) (emphasis added).

Nevertheless, we are not persuaded that we abused our discretion in concluding that substantially the same arguments were previously presented, either. Petitioner contends that it submitted expert testimony that was not previously before the Office during examination. Reh’g Req. 2–3. In particular, Petitioner argues that the Office “never considered whether discovery of the alleged ‘unexpected benefits’ . . . was itself ordinary and routine, and thus not sufficient to overcome the strong *prima facie* case that the ’040 Patent claims are obvious and unpatentable.” *Id.* Petitioner also claims that this evidence and “its implications” were discussed in the Petition. *Id.* at 3 (citing Paper 6 (“Pet.”), 11–13).

Petitioner’s argument, however, does not appear on the cited pages of the Petition, which describe the “background science” of stereochemistry, new drug research, and β -blockers. *See* Pet. 11–13. Nor does it appear in the section arguing that the alleged unexpected results do not overcome the *prima facie* case of obviousness. *See id.* at 55–56. At most, the Petition

¹ Van Lommen et al., US 4,654,362, issued Mar. 31, 1987 (Ex. 1004).

asserts that the claimed compounds would have been the intended and expected result of combining the references. *See id.* at 56 (stating “the compounds of Claim[s] 1 and 2 would be the intended and expected result of combining the prior art asserted herein”). That assertion differs from what Petitioner now argues in its Request—i.e., that the discovery of the alleged unexpected benefits would have been routine and ordinary. *See* Reh’g Req. 3–4. Thus, because it was not made in the Petition, we could not have misapprehended or overlooked Petitioner’s new argument. *See* 37 C.F.R. § 42.71(d).

Regardless, as we noted in our Decision, “the examiner repeatedly stated that ‘the skilled artisan would have seen optical isomer separation as a routine procedure leading to the compounds claimed herein.’” Dec. 9 (citing Ex. 1002, 48, 73, 88, 113). We also noted that by accepting without deciding that the examiner established a *prima facie* case of obviousness, the Board assumed that a person of ordinary skill in the art would have considered separating and studying the stereoisomers of the prior art base compound to be ordinary and routine. *Id.* at 11–12. To the extent Petitioner contends that its argument in its Rehearing Request differs from that offered by the examiner during prosecution, both arguments rest on the same assertion that separating and studying stereoisomers would have been ordinary and routine. The Board considered that assertion to be true, but determined that the evidence of unexpected benefits outweighed that assertion. Given the similarity of Petitioner’s and the examiner’s arguments, we see no reason to second-guess the prior panel’s determination, particularly where § 325(d) only requires that the arguments be substantially the same, and not identical.

Moreover, as explained in our Decision, the Petition failed to address the deficiencies in the examiner's position that the prior panel expressly identified in its decision on appeal. *See* Dec. 12. That is, the Petition failed to address why an ordinary artisan "would have expected the RSSS stereoisomer to have such [potentiating] properties" or to show "that the potentiating property, described in the declaration, is insignificant." *Id.* (quoting Ex. 1002, 200). In its Request, Petitioner claims that our Decision was incorrect because Petitioner addressed those deficiencies in the Petition. *Reh'g* Req. 3–4 (citing Pet. 55–56). But the cited pages of the Petition argue the secondary considerations evidence is irrelevant because there is no nexus, and because the claimed compounds would be the expected result of combining the references. Pet. 55–56. We did not, however, find those arguments persuasive, and the Petition was otherwise silent as to the examiner's deficiencies.

Petitioner also argues that the Decision "provides no explanation as to why the alleged 'unexpected benefits' evidence, even if taken at face value, is sufficient to overcome the strong *prima facie* showing of obviousness," particularly in light of the argument in the Petition that the evidence of unexpected benefits has no nexus to the challenged patent claims. *Reh'g* Req. 4–5. Our Decision, however, explains that the prior panel rejected the examiner's argument that there was no nexus between the unexpected benefits and the natural racemic mixture. Dec. 10-11. We also found that the prior panel implicitly determined there was a sufficient nexus by concluding the applicants' evidence of secondary considerations was sufficient to overcome the *prima facie* case of obviousness. *Id.* To the extent Petitioner asserts that we should have provided a separate analysis of the unexpected benefits evidence, Congress permits us to exercise our

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