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Paper 52
Entered: March 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

Case PGR2018-00001
Patent 9,539,268 B2

Before TONI S. SCHEINER, GRACE KARAFFA OBERMANN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Patent Owner filed a Request for Rehearing (Paper 49, "Req. Reh'g") seeking review of the Board's Final Written Decision (Paper 48, "Dec."), in which we held unpatentable claims 3–30 of U.S. Patent No. 9,539,268 B2 (Ex. 1001, "the '268 Patent"). With Board pre-authorization (Paper 50), Petitioner filed a Response to the Request for Rehearing. Paper 51 ("Reh'g Resp."). This Decision also refers to the Petition (Paper 2, "Pet."), the Patent Owner's Response (Paper 22, "Resp."), Petitioner's Reply (Paper 36, "Reply"), and Patent Owner's Sur-Reply (Paper 39, "Sur-Reply").

Upon request for rehearing, we review our decision for an abuse of discretion. 37 C.F.R. § 42.71(c). "The burden of showing a decision should be modified lies with the party challenging the decision." 37 C.F.R. § 42.71(d). "The request must specifically identify 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." *Id*. Based on an application of those principles, we deny the Request for Rehearing.

II. DISCUSSION

The claimed invention relates to unenhanced dosage forms of zolendronic acid that achieve a bioavailability in humans "from about 1.1% to about 4%." Dec. 6 (quoting claim 1). In a nutshell, we found that the written description of the '268 Patent lacks guideposts sufficient to enable an ordinarily skilled artisan to practice the claimed invention, because the description does not explain how to differentiate dosage forms that achieve the required bioavailability from those that do not. *Id*. at 12–21.

Patent Owner requests modification of the Final Written Decision on four grounds. First, Patent Owner submits, the Board misattributed a statement made by Petitioner's witness to Patent Owner's witness. Req. Reh'g 2–3. Second, Patent Owner contends that the Board overlooked or misapprehended information bearing on the issue of enablement. *Id*. at 3–11. Third, Patent Owner argues that the Board overlooked or misapprehended an alleged admission by Petitioner that an ordinarily skilled artisan "could achieve a bioavailability above 1% for zoledronic acid without using a bioavailability enhancing agent." *Id*. at 12. Fourth, Patent Owner argues that the Board misapplied or misunderstood principles governing the evidentiary showing applicable to enablement. *Id*. at 13. We address in turn each of those asserted grounds for modification.

A. Alleged Misattribution of Testimonial Evidence

We agree with Patent Owner that, in one instance, the Board misattributed testimony of Petitioner's witness, Dr. Clive G. Wilson, to Patent Owner's witness, Dr. William Wargin. Req. Reh'g 2 (citing Dec. 14). That circumstance does not persuade us of reversible error, however, or otherwise compel modification of the Final Written Decision.

Dr. Wilson, not Dr. Wargin, likened the belief that unenhanced zolendronic acid dosage forms could achieve bioavailabilities as high as 1.1% to "a belie[f] in 'fairies.'" Req. Reh'g 2 (quoting Dec. 14; Ex. 2014, 137:21–138:8). That testimony represents a small fraction of the totality of evidence that undergirds our finding that an ordinarily skilled artisan generally would have expected that attaining a human bioavailability for zolendronic acid above 1% required an enhancer. *See* Dec. 12–21 (citing

substantial evidence for that proposition). Even if we set aside the testimony misattributed to Dr. Wargin, substantial evidence supports that finding.

Patent Owner unequivocally admitted as much, stating that an ordinarily skilled artisan at the time of the invention would have "believed that the oral bioavailability in humans of *all* forms for zoledronic acid could not be above 1% without an enhancer." Resp. 1 (emphasis in original). That admission is consistent with other persuasive evidence on point, including the Specification of the '268 Patent, which indicates that the bioavailability of unenhanced zolendronic acid forms is low, with some forms having a bioavailability as low as 0.01%. Dec. 13 (citing Ex. 1001, 13:57–59), 14 (citing Ex. 1001, 14:8–11).

The Final Written Decision turns on the lack of guideposts in the Specification (for example, the absence of any pharmacokinetic data or disclosure of even one example of a dosage form that meets the challenged claims). *Id*. at 13–14 (citing Ex. 1005 ¶¶ 64–65, 69). The lack of a working example, however, is just one fact contributing to the totality of circumstances that support our holding of non-enablement. At its core, this case turns on the lack of disclosure in the Specification combined with the unpredictable nature of the field of invention of pharmaceutical formulation. *Id*. at 12. Substantial evidence of record points in one direction; that an ordinarily skilled artisan generally would have expected unenhanced zoledronic acid dosage forms to exhibit a bioavailability in humans of 1% or lower. *Id*. at 12–13. Neither the Specification, nor any general understanding in the art, would have equipped an ordinarily skilled artisan to distinguish unenhanced dosage forms that achieve the bioavailability required by the

challenged claims from those that do not, absent undue experimentation. *Id*. at 13–21.

Alternatively, the testimony at issue carries some weight even when properly attributed to Dr. Wilson. Significantly, on that point, Dr. Wargin's testimony aligns with Dr. Wilson's testimony. Dr. Wargin similarly testifies that an ordinarily skilled artisan "would not have expected that the oral bioavailability of zolendronic acid could be above 1% in human beings without using an enhancer." Reh'g Resp. 1–2 (quoting Ex. 2017 ¶ 98). The witnesses, in essence, agree on the underlying technical fact at hand. Patent Owner does not show reversible error based on the isolated instance in which the Board misattributed Dr. Wilson's testimony to Dr. Wargin.

In sum, substantial evidence supports our determination that the disclosure of the '268 Patent lacks guideposts sufficient to illuminate a path toward unenhanced dosage forms that fall within the scope of the challenged claims. *See* Dec. 15–20 (citing evidence on point). Accordingly, as Petitioner points out, the misattribution of testimony was inconsequential. Sur-Reply 1 (heading).

B. Alleged Failure to Comprehend Evidence of Enablement

Patent Owner asserts that the Board, in four instances, reversibly erred by overlooking or misapprehending arguments and evidence pertaining to enablement. Req. Reh'g 3–4. All four instances generally relate to our finding that an ordinarily skilled artisan would have expected unenhanced zoledronic acid "to have an oral bioavailability of less than 1%" and that the '268 Patent lacks guidance sufficient to explain how to identify unenhanced dosage forms that meet the claim limitation requiring a bioavailability in humans from about 1.1% to about 4%. Req. Reh'g 3

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