UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), INC.
Petitioner

v.

GILEAD PHARMASSET LLC
Patent Owner

Case No. IPR2018-00126
U.S. Patent No. 9,284,342

PETITIONER'S REQUEST FOR REHEARING

I. INTRODUCTION

Petitioner Initiative for Medicines, Access & Knowledge (I-MAK), Inc. ("Petitioner") respectfully requests rehearing of the Board's Decision Denying Institution of *Inter Partes* Review ("IPR") of Gilead Pharmasset LLC's ("Gilead") U.S. Patent 9,284,342 ("the '342 patent") ("Decision"; Paper 7) because the Board misapprehended or overlooked Petitioner's evidence of motivation to pursue alternative crystalline forms that would lead a POSA to the '342 patent's claims.

II. LEGAL STANDARD

A party may request rehearing of a denial of institution by, "identify[ing] 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). The Board reviews its decision for "abuse of discretion," *Id*. at § 42.71(c), which includes basing the decision on, "an erroneous conclusion of law or clearly erroneous factual finding." *PPG Indus., Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988).

III. PETITIONER'S EVIDENCE IS NOT CUMULATIVE AND INDEED DIRECTLY REBUTS THE EXAMINER'S UNSUPPORTED SOLE REASON FOR ALLOWANCE

In denying institution, the Board stated in the Decision that, "the argument that a POSA *could* have prepared the S*p*-4 compound having that structure is unpersuasive because 'obviousness concerns whether a skilled artisan not only

could have made but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.'" Paper 7, 17 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)) (emphasis in original). However, the Board misapprehended or overlooked Petitioner's evidence of motivation to make alternative crystalline forms that would lead a POSA to the '342 patent's claims.

For one, the Board did not address Petitioner's argument that:

> Because the amount of residual dichloromethane in a standard dose of PSI-7977 as the dichloromethane solvate, known as of 2010 to be either 200 or 400 mg/day of active drug, EX1023, was several times greater than the Permissible Daily Exposure limit of 6 mg, a POSA would have been compelled to create alternative crystalline forms of PSI-7977 for human use.

Ex. 1002, ¶ 95. Thus, the toxicity of the dichloromethane solvate of PSI-7977 as revealed by comparison of the level of dichloromethane exposure in a typical daily dose and the recommended maximum human exposure allowable according to the ICH Guidelines, Ex. 1022, would have motivated a POSA to pursue additional crystalline structures. As Dr. Fortunak explained:

> A POSA would also have known that dichloromethane is a "class II" solvent whose exposure to a patient should be limited due to inherent toxicity. "Specifications: Test Procedures and Acceptance Criteria For New Drug Substances and New Drug Products: Chemical Substances," ICH (Q6A) Harmonised Tripartite Guideline, October 6, 1999 ("ICH"; EX1022).

Ex. 1002, ¶ 94. The known crystalline form in the prior art was therefore

unacceptable for human use because of the toxicity of the dichloromethane contained in such crystalline form. In making this argument, Petitioner provided additional evidence of motivation for a POSA to pursue alternative crystalline forms:

> The dichloromethane solvate of PSI-7977 contains approximately 13.8% of dichloromethane by weight. Thus, a 200mg daily dose of active PSI-7977 would contain 32mg of dichloromethane – several times the acceptable limit for daily exposure.

Ex. 1002, ¶ 95 n1.

Petitioner also provided additional evidence of why a POSA would have been motivated, indeed obligated, to investigate the effects of water and humidity on the properties of an Active Pharmaceutical Ingredient (API) as a requirement for filing an Investigational New Drug Application to utilize PSI-7977 for human dosing. Ex. 1002, ¶ 96. In the course of doing so, a POSA would have naturally discovered the crystalline forms claimed in the '342 patent. Ex. 1002, ¶ 96. The Board in its Decision did not identify, much less address, this evidence of motivation for a POSA to pursue additional crystalline forms.

In short, while claiming Petitioner's evidence is conclusory, the Board did not address all of Petitioner's evidence.

In addition, the Board also erroneously dismissed Petitioner's evidence, including Dr. Fortunak's opinions, because they were stated verbatim in the Petition. Paper 7, 13. The fact that an expert's opinion testimony is cited

unchanged in a Petition is not a basis to ignore it. Indeed, one would hope a Petition would repeat expert testimony rather than rephrase it in ways that could have scientific consequences. No where did the Board cite any evidence contradicting Dr. Fortunak's opinions. The Board's decision to give it no weight was, thus, an abuse of discretion, especially since even Patent Owner did not dispute Dr. Fortunak's credentials.

The Board's only other criticism of Dr. Fortunak's testimony is that it was supposedly "without citing evidentiary support." Paper 9, 10, 13 and 15. However, many of the cited paragraphs of Dr. Fortunak's declaration absolutely do cite evidence. *See*, *e.g.*, Paper 7, 13 (describing Ex. 1002, ¶ 137 as "without citing evidentiary support," when that paragraph of Dr. Fortunak's declaration directly cites Sofia '634 and Ma). Regardless, Dr. Fortunak's testimony is itself evidence. Patent Owner does not dispute Dr. Fortunak is an expert with substantial education and decades of experience underlying his opinions. To dismiss his opinions as baseless contradicts centuries of American jurisprudence giving substantial weight to the opinions of experts, especially when they are unrebutted and unimpeached as here.

Patent Owner provides, and the Board cites, no evidence to contradict the evidence provided by Petitioner showing there was motivation to achieve the claims of the '342 patent. That evidence is substantial and supports a finding that

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