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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES, INC.,
Petitioner,

v.

VANDA PHARMACEUTICALS INC.,
Patent Owner.

Case IPR2016-00690
Patent 9,138,432 B2

Before RAMA G. ELLURU, SHERIDAN K. SNEDDEN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Roxane Laboratories, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claim 1 of U.S. Patent No. 9,138,432 B2 (Ex. 1001, "the '432 patent"). Paper 2 ("Pet."). Vanda Pharmaceuticals Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). The Board denied the Petition. Paper 8 ("Dec."). Petitioner filed a Request for Rehearing. Paper 9 ("Reh'g Req."). Patent Owner filed a reply. Paper 10 ("Reply").

Although we consider Petitioner's arguments below, the Request for Rehearing is *denied.*

II. STANDARD OF REVIEW

When considering a request for rehearing on whether to institute trial, the Board reviews its decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if the decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *see also PPG Indus., Inc. v. Celanese Polymer Specialties Co., Inc.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (stating that an abuse of discretion may arise where a decision was based on an erroneous conclusion of law, clearly erroneous factual findings, or a clear error of judgment.)

III. ANALYSIS

The '432 patent discloses methods for lowering the risk for QT prolongation associated with the administration of iloperidone in patients with lower than normal CYP2D6 activity arising from a patient's genetic

background, or by the concomitant administration of a CYP2D6 inhibitor, such as fluoxetine. Ex. 1001. The challenged claim relates to a method for decreasing the risk of QT prolongation in a patient via a dose reduction in patients' co-administered fluoxetine, in particular, by:

> administering to the patient a dose of iloperidone that is 24 mg/day if, and because, the patient is not being treated with fluoxetine; and
>
> administering to the patient a dose of iloperidone that is 12 mg/day if, and because, the patient is being treated with fluoxetine.

Id., claim 1.

Petitioner contends that the Board erred in overlooking its argument that one of ordinary skill in the art would have arrived at the claimed reduction by routine experimentation. We do not find Petitioner's argument persuasive.

We concluded that the record as a whole, including FDA Guidance 1999, supported a mere invitation to experiment as rejected in *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1073 (Fed. Cir. 2012). Dec. at 19, 22–23; *see id*. at 22 ("Such invitations to experiment do not, in light of the present record, predict the dosage reduction of the subject claim.").

The Decision, including our citation to *Cylobenzaprine*, makes clear our implicit rejection of Petitioner's argument that, "to arrive at the claimed dosages, a POSA need only have followed FDA Guidance 1999's comprehensive guidelines for the performance of drug interaction and dose regimen studies" using only "routine experimentation" and with "predictable results." Pet. 54–55, 58; Reh'g Req. 4–5. Petitioner's reliance on *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804 (Fed. Cir. 1989) and *Genzyme*

Therapeutic Prods. LP v. Biomarin Pharm. Inc., 825 F.3d 1360 (Fed. Cir. 2016) underscore our reasoning. *See* Reh'g Req. 8–9.

Genzyme involved the question of whether one of ordinary skill in the art would have arrived at the claimed dosing parameter for enzyme replacement treatment of Pompe's disease with GAA (human acid alpha glucosidase) by routine optimization. *Genzyme* 825 F.3d at 1365. The Genzyme Court noted that dosing schedules for enzyme replacement therapy of a similar lysosomal protein deficiency condition were known, as was the biological half-life of GAA. *Id*. at 1364. This factual background "provided a sound basis for belief that a dosage interval of one to two weeks would be effective. In sum, there was little left to do but to confirm that the strategy suggested by the various prior art references would work." *Id*. at 1373.

Merck involved the co-administration of two diuretic compounds, whose combined effect "was to be expected from the known natriuretic properties of the two diuretics." *Merck*, 874 F.2d at 809. Thus, as with *Genzyme*, to determine the appropriate dosing, "routine procedures . . . produc[ed] only predictable results." *Id*.

Unlike in *Merck* and *Genzyme*, the present case does not involve predictable results that may be confirmed or fine-tuned by routine experimentation. Rather, upon careful consideration of the asserted prior art as a whole, we determined that, "it could not be predicted whether a change in iloperidone metabolism would have increased, decreased, or had no effect on the risk of QT prolongation" and, thus, the amount of dose reduction (if any) was unpredictable and would need to be determined empirically. Dec. at 22–23 (quoting Prelim. Resp. 15–16); *see also id*. at 22 (stating that, "the art as a whole taught a careful evaluation of [drugs such as iloperidone] for evidence of clinically-relevant drug-drug interactions, which may or may not

be addressed with dose reductions").[1] Thus, our determination rejects Petitioner's contention that one of ordinary skill in the art would have arrived at the claimed dosage reduction by routine experimentation. *See Coherus Biosciences, Inc., v. Abbvie Biotechnology LTD.*, Case IPR2016-00189, slip op. at 2 (PTAB July 14, 2016) (Paper 27) ("The Board is not obligated to respond in writing to every unpersuasive argument made before it."). Accordingly, we are not persuaded we misapprehended or overlooked any of Petitioner's arguments.

IV. CONCLUSION

For the reasons set forth above, Petitioner has not shown that the Board's determination that Petitioner has failed to demonstrate that at least one of the challenged claims is unpatentable is based on an erroneous interpretation of law, factual findings not supported by substantial evidence, or unreasonable judgment in weighing relevant factors. The Request is *denied*.

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[1] Our conclusion is underscored by Patent Owner's evidence that when Novartis conducted the type of study suggested by FDA Guidance 1999, it reached "exactly the wrong conclusion," with respect to the need for iloperidone dosing adjustments. *See* Prelim. Resp. at 46–47 (citing Ex. 2001 ¶¶ 88–90); Reply 8–9 (same).

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