Paper No. 10
Entered: October 13, 2016

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 No. 9,138,432

PATENT OWNER VANDA PHARMACEUTICAL'S RESPONSE TO ROXANE'S REQUEST FOR REHEARING OF THE DECISION DENYING INSTITUTION

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Because the Decision Denying Institution of *Inter Partes* Review (Paper 8) shows that the Board understood and considered the arguments and evidence that Roxane now argues it overlooked, Roxane's Request for Rehearing (Paper 9) should be denied.

1. The Board Did Not Overlook Roxane's Arguments And Evidence

Roxane's Petition argued that "[i]n order 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. at 54–55 (Ground I), 58 (Ground II). Roxane now asserts that the Board overlooked these arguments and supporting evidence. Rehearing Req. at 4–5. But the Decision shows that the Board considered and rejected them.

First, the Decision provides an extensive summary of FDA Guidance 1999, including its recommendations and guidance regarding *in vivo* metabolic drug-drug interaction studies, the general concepts underlying its recommendations, its goal of determining the clinical significance of any increase or decrease in exposure to a substrate in the presence of an interacting drug, and examples of drug-drug interactions involving the P450 enzymes CYP3A4 and CYP2D6. Decision at 10–

12. This shows that the Board considered the disclosures of FDA Guidance 1999, and did so in detail.

Second, the Decision provides an extensive summary of Roxane's arguments regarding FDA Guidance 1999, including those that Roxane now contends the Board overlooked:

- "In particular, Petitioner argues that, as reflected in FDA Guidance 1999, 'in order to safely administer a drug like iloperidone to a patient, a POSA needed to first review the drug's metabolic pathways, identify all of the patient's concurrent medications, and determine what dose adjustments might be necessary based on potential drug interactions.'" Decision at 16 (quoting Pet. at 40–41).
- "Petitioner further argues that 'analysis of a drug's metabolic interactions and dosing adjustments was a routine part of drug development explicitly recommended by the FDA' and, therefore, 'POSAs involved in the development of a drug like iloperidone were motivated to combine the teachings of FDA Guidance 1999, Mutlib, Brosen, and

Mealy in order to secure FDA approval.'" Decision at 17 (quoting Pet. at 42–43) (emphasis added).

- "With respect to Ground II . . . Petitioner takes a similar position with respect to motivation to combine, in particular, that 'FDA Guidance 1999 comprehensively motivates review of these references, instructing on the study of drug interactions both as part of standard clinical practice and in order to secure a drug's FDA-approval.'" Decision at 17–18 (quoting Pet. at 45) (emphasis added).

These excerpts show that the Board was aware of and gave detailed consideration to the arguments Roxane now asserts it overlooked.

Third, the Decision shows that, having considered Roxane's arguments that the claimed dosages were the result of routine experimentation, the Board denied institution, not because the Board misunderstood Roxane's arguments, but because it found Vanda's arguments more persuasive. As the Board explained:

In response, Patent Owner argues that FDA Guidance 1999, Petitioner's primary reference, provides only an "invitation to experiment" without any indication of whether the interaction of fluoxetine with iloperidone would be clinically meaningful "or what

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