

**On Behalf Of:**

Noven Pharmaceuticals, Inc.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**NOVEN PHARMACEUTICALS, INC.,  
Petitioner**

**v.**

**NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,  
Patent Owners**

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**Inter Partes Review No.: 2014-00549**

**U.S. Patent 6,316,023**

**PETITIONER'S REPLY**

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## **I. Introduction**

Patent Owners do not challenge the scientific basis for the POSA's reasonable expectation of rivastigmine's susceptibility to oxidative degradation, and either mischaracterize the prior art (and Dr. Kydonieus' explanations thereof) or raise speculative alternative explanations that find no basis in the prior art's plain-language text. This is nothing more than collateral evidence designed to distract from the teachings of the prior art and the reasonable expectations the POSA would have maintained based on that art.

Patent Owners do not challenge that Enz is a proper starting point for this obviousness analysis, and do not dispute that it would have been routine work for the POSA to select an antioxidant that works in a particular formulation. Patent Owners do not assert that any elements of the challenged '023 patent claims are not found in the prior art, or that any particular feature of dependent claims 2, 4, 5, 7, or 8 separately supports patentability. Further, Patent Owners have waived any arguments for secondary considerations of non-obviousness by not presenting them in their Response. (Paper 11 at 3 "any arguments for patentability not raised in the response will be deemed waived.")

Patent Owners rely on the purported lack of motivation to add an antioxidant to a rivastigmine pharmaceutical composition. But as Petitioners have shown, the evidence that a POSA would have maintained a reasonable expectation of

rivastigmine's propensity to oxidatively degrade extinguishes any notion that observing rivastigmine's degradation is the basis of an invention, and thus claims 1, 2, 4, 5, 7, and 8 of the '023 patent are unpatentable.

## **II. Observing Rivastigmine's Oxidative Degradation Is Not A Patentable Invention**

The observation of a problem is not *per se* a patentable invention. (Paper 25 at 5.) Rather, the obviousness inquiry must consider whether the POSA would have reasonably expected the problem or what the prior art as a whole would have suggested to the POSA. *See, e.g., Chapman v. Casner*, 315 F. App'x. 294, 298-299 (Fed. Cir. 2009) (Rader, Cir. J., dissenting, noting that whether a POSA would have expected a problem is part of the obviousness analysis); *In re Peehs*, 612 F.2d 1287, 1290 (C.C.P.A. 1980) (determinative question for obviousness was whether cause of problem would have been recognized by POSA); *In re Nomiya*, 509 F.2d 566, 571-72 (C.C.P.A. 1975) (obviousness inquiry hinged on whether the prior art suggested the existence of the problem solved).

*Leo Pharm. Prods. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013) is not on point. In that case, the prior art's failure to recognize the stability issue was attributed to its consistent teaching away from mixing Vitamin D analogs with other drugs in the first place. *Id.* at 1353-54, 55, 57. Further, the court found that the eventual solution (use of a particular solvent) was not known or predictable. *Id.* at 1356-57. Finally, the court found the most probative evidence of nonobviousness was

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