

On Behalf Of:

Noven Pharmaceuticals, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**NOVEN PHARMACEUTICALS, INC.,
Petitioner**

v.

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

***Inter Partes* Review No.: 2014-00550
U.S. Patent No. 6,335,031**

PETITIONER'S REPLY

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. OBSERVING RIVASTIGMINE’S OXIDATIVE DEGRADATION IS NOT A PATENTABLE INVENTION	2
III. A POSA WOULD HAVE REASONABLY EXPECTED RIVASTIGMINE TO OXIDATIVELY DEGRADE BASED ON ITS CHEMICAL STRUCTURE	4
A. Dr. Schoneich’s Opinions Are Not “Theoretical”	4
B. The Known Susceptibility of Nicotine to Oxidation Would Have Informed the POSA’s Expectation About Rivastigmine	5
C. Testing Would Not Have Been Required for a POSA to Determine that Rivastigmine Is Particularly Susceptible to Oxidation	6
D. Susceptibility to Oxidation Would Have Been Predicable	7
IV. THE PRIOR ART DOES NOT TEACH THAT RIVASTIGMINE IS OXIDATIVELY STABLE	9
V. A POSA WOULD HAVE BEEN MOTIVATED TO COMBINE THE TEACHINGS OF THE PRIOR ART TO ARRIVE AT THE CLAIMED INVENTION	10
A. A POSA Would Not Draw the Artificial Distinctions Among the Prior Art that Patent Owners Assert	11
B. Patent Owners Cannot Avoid the Plain Language of Rosin, Elmalem, and Sasaki	12
VI. THE PRIOR ART DID NOT DISCOURAGE THE USE OF ANTIOXIDANTS	14
VII. CONCLUSION	15

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>In re Omeprazole Patent Litig.</i> , 536 F.3d 1361 (Fed Cir. 2008)	3
<i>Activevideo Networks, Inc. v. Verizon Commc'ns., Inc.</i> , 694 F.3d 1312 (Fed. Cir. 2012)	11
<i>Arlington Indus., Inc. v. Bridgeport Fittings, Inc.</i> , 581 F. App'x. 859 (Fed. Cir. 2014)	3
<i>Chapman v. Casner</i> , 315 F. App'x. 294 (Fed. Cir. 2009)	2
<i>In re Nomiya</i> , 509 F.2d 566 (C.C.P.A. 1975)	2
<i>In re Peehs</i> , 612 F.2d 1287 (C.C.P.A. 1980)	2
<i>Innogenetics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	11
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	10
<i>Leo Pharm. Prods. v. Rea</i> , 726 F.3d 1346 (Fed. Cir. 2013)	2, 3

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 '031 patent claims are not found in the prior art, or that any particular feature of dependent claims 2-3, 7, 14, 16 or 18 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 1-3, 7, 14-16 and 18 of the '031 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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.