

**On Behalf Of:**

Novartis AG and LTS Lohmann Therapie-Systeme AG

**By:**

Raymond R. Mandra  
ExelonPatchIPR@fchs.com  
(212) 218-2100

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. 2014-00549

U.S. Patent 6,316,023

PATENT OWNERS' RESPONSE  
PURSUANT TO 37 C.F.R. § 42.220

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	THE RELEVANT LEGAL STANDARDS .....	5
	a. The discovery of an unknown problem can constitute a non-obvious invention.....	5
	b. Obviousness requires proof of a motivation for a POSA to have combined the claim elements .....	6
	c. If testing is required to discover the problem solved by the claimed invention, then the invention is not obvious.....	7
	d. The existence of FDA guidance as to a general course of action does not suffice to render obvious a patent that solves a specific problem .....	9
III.	THE TRUE STATE OF THE ART.....	10
	a. The art taught not to use excipients unless they are required.....	10
	b. The art taught not to use antioxidants unless they are required.....	11
	c. The art taught that oxidation is formulation-specific.....	13
	d. The art taught that rivastigmine was chemically stable .....	14
	e. A POSA would not reasonably have predicted that rivastigmine would oxidatively degrade based on its structure .....	16
IV.	PETITIONER’S CITED PRIOR ART .....	20
	a. Enz.....	21
	b. The Handbook .....	23
	c. Rosin.....	24
	d. Elmalem.....	28

e.	Ebert .....	37
f.	Sasaki.....	41
g.	Kissel.....	44
V.	CONCLUSION.....	45

## I. INTRODUCTION

Novartis AG and LTS Lohmann Therapie-Systeme AG (“Patent Owners”) respectfully submit this 37 C.F.R. § 42.220 response to the April 2, 2014 petition of Noven Pharmaceuticals Inc. (“Petitioner”) seeking *inter partes* review (“IPR”) of U.S. Patent No. 6,316,023 (“’023 Patent”).

The Board in an October 14, 2014 decision (Paper 10) instituted IPR against the ’023 Patent on the following Grounds:

Ground	References	Basis	Claims
1	Enz and the Handbook, optionally in view of Rosin and/or Elmalem and/or Ebert	§ 103(a)	1, 7
2	Enz and the Handbook, and/or Rosin, and/or Ebert	§ 103(a)	2
3	Enz and the Handbook and/or Ebert	§ 103(a)	4, 5
4	Enz, the Handbook, and Ebert or Kissel	§ 103(a)	8
5	Enz and Sasaki	§ 103(a)	1, 2, 4, 5 and 7
6	Enz, Sasaki, and Ebert or Kissel	§ 103(a)	8

No challenged claim is obvious on any of these Grounds, for the following reasons:

- The '023 Patent is directed to and claims pharmaceutical compositions, particularly transdermal devices, comprising rivastigmine and an antioxidant.
- The relevant invention date for assessing the alleged obviousness of the '023 Patent is January 12, 1998. (Ex. 2012 ¶ 23.)
- As of 1998, the art taught a person of ordinary skill in the art (“POSA”) not to include an antioxidant in a pharmaceutical formulation unless one was required. (Ex. 2012 ¶¶ 37-46.)
- As of 1998, the art as a whole did not teach or suggest to the POSA that rivastigmine underwent oxidative degradation under pharmaceutically relevant conditions or required an antioxidant. (Ex. 2012 ¶ 47.) To the contrary, the art as a whole—including Rosin and Elmalem—taught that rivastigmine was chemically stable and did not require an antioxidant in any pharmaceutical composition. (Ex. 2012 ¶ 47.)
- As of 1998, a POSA would not reasonably have predicted from the chemical structure of rivastigmine that rivastigmine would oxidatively degrade under pharmaceutically relevant conditions or require an antioxidant. (Ex. 2012 ¶¶ 119-160.) To the contrary, Petitioner’s experts in this IPR admitted at trial in a parallel litigation, *Novartis Pharmaceuticals Corp. v. Noven Pharmaceuticals Inc.*, 13-cv-527 (D.

# 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.