

On Behalf Of:

Novartis AG and LTS Lohmann Therapie-Systeme AG

By:

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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 6,335,031

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

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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. 6,335,031 (“’031 Patent”).

The Board in an October 14, 2014 decision (Paper 10) instituted IPR against the ’031 Patent on the following Grounds:

Ground	References	Basis	Claims
3	Enz and the Handbook, optionally in view of Rosin and/or Elmalem and/or Ebert	§ 103(a)	1, 2, 7, 15, 18
4	Enz and the Handbook and/or Rosin and/or Ebert	§ 103(a)	3, 16
5	Enz and Sasaki	§ 103(a)	1-3, 7, 14, 16, 18

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

- The ’031 Patent is directed to and claims pharmaceutical compositions, particularly transdermal devices, comprising rivastigmine and an antioxidant. (Ex. 1001 at col. 8, l. 34-col. 10, l. 13.)
- The relevant invention date for assessing the alleged obviousness of the ’031 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. Del.), that a POSA would need to conduct testing to determine whether rivastigmine oxidatively degrades under pharmaceutically relevant conditions. (Ex. 1025 at 95:24-96:18, 232:6-13, 258:8-13, 283:14-284:19, Ex. 1029 at 53:10-17.) It is undisputed that no such testing was reported in the art as of 1998. (Ex. 2012 ¶ 47.)

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