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Paper 10
Entered: October 14, 2014

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.

Case IPR2014-00550
Patent 6,335,031 B1

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and SCOTT E. KAMHOLZ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Noven Pharmaceuticals, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–3, 7, 15, 16, and 18 of U.S. Patent No. 6,335,031 (Ex. 1001, "the '031 patent"). Paper 1 ("Pet."). Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively, "Patent Owner"), filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–3, 7, 15, 16, and 18 of the '031 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

According to Petitioner and Patent Owner, the '031 patent is involved in various district court actions, including two actions involving the parties to this proceeding, titled: *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:13-cv-00527 (D. Del.); and, *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:14-cv-00111 (D. Del.). Pet. 1–2; Paper 6 at 2.

Additionally, Petitioner has filed a petition for *inter partes* review of related U.S. Patent No. 6,316,023. IPR2014-00549, Paper 1.

B. The '031 Patent (Ex. 1001)

The '031 patent is directed to a pharmaceutical composition comprising (S)-N-ethyl-3-[(1-dimethylamino)ethyl]- N-methyl-phenyl-carbamate ("compound A"; "rivastigmine"; "S-enatiomer of RA_7") in the form of a free base or acid addition salt, an antioxidant, and a diluent or carrier. Ex. 1001, 1:7–47. "Compound A is useful in inhibiting acetylcholinesterase in the central nervous system, e.g. for the treatment of Alzheimer's disease." *Id*. at 1:14–16. A transdermal composition comprising compound A in the form of a free base or acid addition salt, two polymers, and a plasticizer is disclosed in the prior art. *Id*. at 1:17–21. The inventors of the '031 patent explained that the composition of the prior art "is susceptible to degradation, particularly in the presence of oxygen." *Id*. at 1:22–24.

The '031 patent states:

> The present applicant has found that stable pharmaceutical compositions comprising compound A can now be obtained, which show insignificant degradation of compound A over a prolonged time period, e.g. 2 years, as indicated by standard tests, e.g. stress tests.
>
> In one aspect, the invention provides a pharmaceutical composition comprising Compound A in free base or acid addition salt form and an anti-oxidant.
>
> The pharmaceutical compositions of the present invention show a reduction in degradation by-products in stress stability tests.

Id. at 1:29–39.

The '031 patent discloses that an effective stabilization effect is achieved "when the antioxidant is selected from tocopherol, esters thereof, e.g. tocopherol acetate, ascorbyl palmitate, ascorbic acid, butylhydroxytoluene, butylhydroxyanisone or propyl gallate, preferably α-tocopherol or ascorbyl palmitate." *Id*. at 4:11–16. "The antioxidant may be conveniently present in an amount of from about 0.01 to about 0.5% . . . by weight based on the total weight of the pharmaceutical composition." *Id*. at 4:16–19.

Additionally, the '031 patent teaches that "[t]he pharmaceutical compositions of the invention may contain high amounts of compound A, e.g. from 1 to 40% by weight." *Id*. at 1:40–42.

C. Illustrative Claims

Independent claims 1, 7 and 15 of the '031 patent are illustrative of the claims at issue:

> 1. A pharmaceutical composition comprising:
> (a) a therapeutically effective amount of (S)-N-ethyl-3-{(1-dimethylamino)ethyl}-N-methyl-phenyl carbamate in free base or acid addition salt form (Compound A);
> (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and
> (c) a diluent or carrier.

Ex. 1001, 8:14–21.

> 7. A transdermal device comprising a pharmaceutical composition as defined by claim 1, wherein the pharmaceutical composition is supported by a substrate.

Id. at 8:49–51.

> 15. A method of stabilizing (S)-N-ethyl-3-{(1-dimethylamino)ethyl}-N-methyl-phenyl-carbamate in free base or acid addition salt form (Compound A), wherein the method comprises forming a composition by combining Compound A with an amount of anti-oxidant effective to stabilize Compound A from degradation.

Id. at 9:10–15.

D. The Prior Art

Petitioner relies on the following prior art:

Enz	UK Patent Application GB 2,203,040 A, published Oct. 12, 1988 ("Enz")	Ex. 1002
Handbook	Handbook of Pharmaceutical Excipients, (A. Wade & P.J. Weller eds., 2d ed. 1944) ("the Handbook")	Ex. 1003
Sasaki	JP Patent Application 58-57689, published Oct. 19, 1984 ("Sasaki")	Ex. 1005
Ebert	WO 95/24172, published Sept. 14, 1995 ("Ebert")	Ex. 1006
Rosin	US 4,948,807, issued Aug. 14, 1990 ("Rosin")	Ex. 1008
Elmalem	*Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents*, 3o NEUROPHARMACOLOGY. 1059-1064 (1991) ("Elmalem")	Ex. 1009

Petitioner also relies on declarations of Dr. Agis Kydonieus (Ex. 1010) and Dr. Christian Schöneich (Ex. 1011).

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