

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

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT 6,316,023 UNDER
35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42**

TABLE OF CONTENTS

TABLE OF CONTENTS	i
LIST OF EXHIBITS	iii
I. MANDATORY NOTICES	1
A. Real Party-In-Interest	1
B. Related Matters	1
C. Lead and Back-Up Counsel	2
D. Service Information	2
II. GROUNDS FOR STANDING	3
III. IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED	3
IV. THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW	3
V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED	4
A. Level of Ordinary Skill in the Art	5
B. Claim Construction	6
C. Scope and Content of the Prior Art	9
1. Rivastigmine Was Being Developed for the Treatment of Alzheimer’s Disease	9
2. Rosin Taught the Use of Antioxidants in Compositions Comprising RA ₇ (Racemic Rivastigmine)	10
3. Elmalem Taught Adding Antioxidants to a Composition Comprising RA ₇ to Prevent Oxidation	11
4. Enz Taught Transdermal Rivastigmine Compositions	12
5. Ebert Taught a Transdermal Drug Delivery System For Liquid, Oxidizable Drugs	13

6.	Sasaki Taught Using the Antioxidant Tocopherol to Promote Storage Stability of the Active Ingredient in Transdermal Compositions.....	16
7.	The Handbook of Pharmaceutical Excipients Detailed Common Antioxidants Used in Approved Pharmaceutical Compositions	17
8.	Kissel Disclosed a Transdermal Drug Delivery System With a Release Liner.....	18
D.	The Challenged Claims are Unpatentable as Obvious Over the Prior Art.....	19
1.	There was motivation to select rivastigmine and modify existing rivastigmine treatments	19
2.	Ground 1: Independent Claims 1 and 7 are Obvious Over Enz and the Handbook, Optionally in View of Rosin and/or Elmalem and/or Ebert.....	21
	(1) No Secondary Considerations Support Non-Obviousness.....	29
3.	Ground 2: Dependent Claim 2 is Unpatentable as Obvious Over Enz and the Handbook and/or Rosin and/or Ebert.....	32
4.	Ground 3: Dependent Claims 4 and 5 are Unpatentable As Obvious Over Enz and the Handbook and/or Ebert.....	34
5.	Ground 4: Dependent Claim 8 is Unpatentable As Obvious Over Enz, the Handbook, and Ebert or Kissel	36
6.	Ground 5: Claims 1, 2, 4, 5, and 7 Are Unpatentable As Obvious over Enz and Sasaki	37
7.	Ground 6: Dependent Claim 8 is Unpatentable As Obvious Over Enz, Sasaki, and Ebert or Kissel	44
VI.	CONCLUSION.....	45

LIST OF EXHIBITS

Noven Exhibit No.	Description
Ex. 1001	U.S. Patent No. 6,316,023, issued November 13, 2001
Ex. 1002	UK Patent Application GB 2,203,040 A, to Enz, published October 12, 1988 (“Enz”)
Ex. 1003	Handbook of Pharmaceutical Excipients, A. Wade and P. J. Weller (eds.) 1994, 2 nd Edition, The Pharmaceutical Press London (the “Handbook”)
Ex. 1004	Japanese Patent Application Publication No. JP 59-184121 to Sasaki et al., published October 19, 1984
Ex. 1005	Certified English Translation of Japanese Patent Application Publication No. JP 59-184121 to Sasaki et al. (“Sasaki”)
Ex. 1006	PCT Publication No. WO 95/024172 to Ebert et al, published September 14, 1995 (“Ebert”)
Ex. 1007	European Patent Application No. 0155 229 A2 to Kissel et al., published September 18, 1985 (“Kissel”)
Ex. 1008	U.S. Patent No. 4,948,807 (“Rosin”)

Ex. 1009	Elmalem et al. 1991, Neuropharmacology 30: 1059-1064 ("Elmalem")
Ex. 1010	Declaration of Agis Kydonieus, Ph.D.
Ex. 1011	Declaration of Christian Schöneich, Ph.D.
Ex. 1012	"Safety/Tolerability Trial of SDZ ENA 713 in Patients with Probable Alzheimer's Disease," John J. Sramek et al., Life Sciences, Vol. 58, No. 15, pp. 1201-1207 (1996) ("Sramek")
Ex. 1013	"New acetylcholinesterase inhibitor shows promise in largest Alzheimer's trial to date," Formulary, Vol. 32, Dec. 1997 ("Formulary Article")
Ex. 1014	ICH Topic Q 1 A, Stability Testing Guidelines: Stability Testing of New Drug Substances and Products (CPMP/ICH/380/95)
Ex. 1015	Connors, Amidon, & Stella, Oxidation and Photolysis in Chemical Stability of Pharmaceuticals – A Handbook for Pharmacists (2nd Edition), John Wiley & Sons, NY (1986), pp. 82-114

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.