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

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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 Ebert21			
	 (1) No Secondary Considerations Support Non- Obviousness			
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Noven **Description Exhibit No.** U.S. Patent No. 6,316,023, issued November 13, 2001 Ex. 1001 UK Patent Application GB 2,203,040 A, to Enz, published Ex. 1002 October 12, 1988 ("Enz") Ex. 1003 Handbook of Pharmaceutical Excipients, A. Wade and P. J. Weller (eds.) 1994, 2nd Edition, The Pharmaceutical Press London (the "Handbook") Japanese Patent Application Publication No. JP 59-184121 to Ex. 1004 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")

LIST OF EXHIBITS

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

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