

Filed 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

EXHIBIT LIST 4

EXHIBIT LIST 4

Pursuant to 37 C.F.R. §42.63(e), Patent Owners Novartis AG and LTS

Lohmann Therapie-Systeme AG submit the following current exhibit list.

Exhibit	Description
2001	Background and Need for the Legislation, House Report of the 112th Congress, 1st Session, Rep. 112-98, Part 1, pp. 40-57 (2011), <i>reprinted in</i> 2011 U.S.C.C.A.N. 70-87
2002	<i>Novartis Pharm. Corp. v. Watson Labs. Inc.</i> , 1:11-cv-01112-RGA (D. Del. June 18, 2014) (Trial Opinion)
2003	Reserved
2004	Reserved
2005	Declaration in Support of Patent Owners' Motion for <i>Pro Hac Vice</i> Admission of Charlotte C. Jacobsen Under 37 C.F.R. § 42.10
2006	Declaration of Agis Kydonieus, Ph.D., Filed in IPR2014-00550 as Ex. 1010 (<i>not filed</i>)
2007	Declaration of Agis Kydonieus, Ph.D., Filed in IPR2014-00549 as Ex. 1010 (<i>not filed</i>)
2008	U.K. Patent Application No. 2,203,040 A (<i>not filed</i>)
2009	U.S. Patent No. 4,948,807 (<i>not filed</i>)
2010	Elmalem, E., <i>et al.</i> , Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents, 30 <i>Neuropharmacology</i> 1059 (1991) (<i>not filed</i>)
2011	U.S. Patent No. 6,335,031 (<i>not filed</i>)
2012	Declaration of Alexander M. Klibanov, Ph.D.

Exhibit	Description
2013	Curriculum Vitae of Alexander M. Klibanov, Ph.D.
2014	Guillory, J. & Poust, R., Chemical Kinetics and Drug Stability, MODERN PHARMACEUTICS, Chapter 6, 179 (Banker, G & Rhodes, C., eds., 3d ed., 1996)
2015	Minutes SDZ ENA 713 TDS LTS-SANDOZ Working Group Meeting (November 28, 1995, Basel), pp. LTS0042712-LTS0042732; ENA713 9mg/5cm ² , 18mg/10cm ² , 27mg/15cm ² , 36mg/20cm ² , Transdermal Patch: Drug product pharmaceutical development (July 4, 2006), pp. LTS0102239- LTS0102258
2016	Food and Drug Administration, Guidance for Industry, Q3C Impurities: Residual Solvents (Dec. 1997)
2017	Remington's Pharmaceutical Sciences, 1507 (Gennaro, A. <i>et al.</i> eds., 18th ed., 1990)
2018	U.S. Patent No. 5,508,038
2019	EMA, Committee for Proprietary Medicinal Products & Committee for Veterinary Medicinal Products, Note for Guidance on Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products (July 8, 1997)
2020	Ansel, H. <i>et al.</i> , PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS, Dosage Form Design, 110 (6th ed., 1995)
2021	Connors, K. <i>et al.</i> , CHEMICAL STABILITY OF PHARMACEUTICALS: A HANDBOOK FOR PHARMACISTS, Chapter 5: Oxidation, 80 (1979)

Exhibit	Description
2022	Physicians' Desk Reference, 486-488, 640-644, 672, 680-684, 842-845, 878-888, 890-891, 974-975, 1336-1340, 1365-1367, 1413-1414, 1439-1442, 1553-1554, 1560, 1568-1570, 1572-1576, 1612-1613, 1623-1624, 1825, 1832-1833, 1878-1881, 1948, 1992-1993, 2007-2008, 2015, 2035-2038, 2042-2043, 2233-2234, 2541-2542, 2634-2636, 2786, 2872-2874, 2885-2886 (51st ed., 1997) (Entries for Prostep [®] , Nicotrol [®] , Habitrol [®] , Duragesic [®] , Transderm-Scop [®] , Catapres-TTS [®] , Androderm [®] , Testoderm [®] , Deponit [®] , Minitran [®] , Nitro-Dur [®] , Transderm-Nitro [®] , Climara [®] , Estraderm [®] , Vivelle [™] , ampicillin, hydroxyzine, meclizine, mirtazapine, benzquinamide, dextromethorphan)
2023	U.S. Pharmacopeial Convention, Revision Bulletin, Clonidine Transdermal System (Jan. 1, 2011) <i>incorporated into</i> United States Pharmacopeia and National Formulary (USP 34-NF 29) Supplement 2, 5407-5410, Rockville, MD: United States Pharmacopeial Convention, 2011
2024	U.S. Patent No. 4,597,961
2025	U.S. Patent No. 6,660,295
2026	Enz, A. <i>et al.</i> , Pharmacologic and Clinicopharmacologic Properties of SDZ ENA 713, a Centrally Selective Acetylcholinesterase Inhibitor, 640 <i>Annals N.Y. Acad. Sci.</i> 272 (1991)
2027	Weinstock, M. <i>et al.</i> , Pharmacological Evaluation Of Phenyl-Carbamates As CNS-Selective Acetylcholinesterase Inhibitors, 43 <i>J. Neural Transmission</i> 219 (1994)
2028	Excerpts from '023 Patent Prosecution History: Application Transmittal & Fee Sheet (December 20, 2000), N0000872 – N0000876; Information Disclosure Statement (December 20, 2000), N0000912-N0000914; Non-Final Office Action (April 9, 2001), N0000917 – N0000923; Supplemental Information Disclosure Statement (May 7, 2001), N0000924 – N0000927

Exhibit	Description
2029	Reserved
2030	European Patent Application No. 0,193,926
2031	U.S. Patent No. 5,939,095
2032	Project SDZ ENA 713 TDS - Technical Development Plan, pp. N0260066-N0260070; Tiemessen Email (December 8, 1997, 1:22 PM), p. N0821943; Overview LTS-Sandoz cooperation on SDZ ENA 713 TDS (Exelon) 1997, pp. N0821944 - N0821949
2033	Main, A., Mode of Action of Anticholinesterases, 6(3) <i>Pharmac. Ther.</i> 579 (1979)
2034	Larson & Weber, REACTION MECHANISMS IN ENVIRONMENTAL ORGANIC CHEMISTRY, Chapter 2: Hydrolysis, 103 (1994)
2035	Chaikin, S., Study of the Hydrolysis of Several Physostigmine Analogs, 69(6) <i>J. Am. Chem. Soc.</i> 1266 (1947)
2036	Weinstock, M. <i>et al.</i> , Pharmacological Activity of Novel Acetylcholinesterase Agents of Potential Use in the Treatment of Alzheimer's Disease, in 29 <i>Advances in Behavioral Biology</i> 539 (1986)
2037	U.S. Patent No. 5,338,548
2038	Wilson & Gisvold, WILSON AND GISVOLD'S TEXTBOOK OF ORGANIC MEDICINAL AND PHARMACEUTICAL CHEMISTRY, 456-457 (Delgado, J. & Remers, W. eds., 9th ed. 1991)
2039	Rogers, A. & Smith, G., The Determination of Physostigmine By Thin-Layer Chromatography and Ultraviolet Spectrophotometry, 87 <i>J. Chromatography</i> 125 (1973)
2040	United States Pharmacopeia and National Formulary (USP 20-NF 15), 624-625, Rockville, MD: United States Pharmacopeial Convention, 1980

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.