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Novartis AG and LTS Lohmann Therapie-Systeme AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS INC.
AND MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review No. 2014-00549[1]

U.S. Patent 6,316,023

EXHIBIT LIST 5

[1] Case IPR2015-00265 has been joined with this proceeding.

EXHIBIT LIST 5

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), *reprinted in* 2011 U.S.C.C.A.N. 70-87
2002	*Novartis Pharm. Corp. v. Watson Labs. Inc.*, 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 *Pro Hac Vice* 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 (***not filed***)
2007	Declaration of Agis Kydonieus, Ph.D., Filed in IPR2014-00549 as Ex. 1010 (***not filed***)
2008	U.K. Patent Application No. 2,203,040 A (***not filed***)
2009	U.S. Patent No. 4,948,807 (***not filed***)
2010	Elmalem, E., *et al.*, Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents, 30 Neuropharmacology 1059 (1991) (***not filed***)
2011	U.S. Patent No. 6,335,031 (***not filed***)
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. *et al.* eds., 18th ed., 1990)
2018	U.S. Patent No. 5,508,038
2019	EMEA, 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. *et al.*, PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS, Dosage Form Design, 110 (6th ed., 1995)
2021	Connors, K. *et al.*, 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) *incorporated into* 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. *et al.*, Pharmacologic and Clinicopharmacologic Properties of SDZ ENA 713, a Centrally Selective Acetylcholinesterase Inhibitor, 640 *Annals N.Y. Acad. Sci.* 272 (1991)
2027	Weinstock, M. *et al.*, Pharmacological Evaluation Of Phenyl-Carbamates As CNS-Selective Acetylcholinesterase Inhibitors, 43 *J. Neural Transmission* 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) *Pharmac. Ther.* 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) *J. Am. Chem. Soc.* 1266 (1947)
2036	Weinstock, M. *et al.*, Pharmacological Activity of Novel Acetylcholinesterase Agents of Potential Use in the Treatment of Alzheimer's Disease, in 29 *Advances in Behavioral Biology* 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 *J. Chromatography* 125 (1973)
2040	United States Pharmacopeia and National Formulary (USP 20-NF 15), 624-625, Rockville, MD: United States Pharmacopeial Convention, 1980

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