

On behalf of: Par Pharmaceutical, Inc. *et al.*

Entered: December 5, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., BRECKENRIDGE PHARMACEUTICAL,
INC., AND ROXANE LABORATORIES, INC.

Petitioners

v.

NOVARTIS AG

Patent Owner

Case IPR2016-00084¹
U.S. Patent No. 5,665,772

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

PETITIONERS' UPDATED EXHIBIT LIST

¹ Breckenridge Pharmaceutical, Inc. was joined as a party to this proceeding via a Motion for Joinder in IPR2016-01023; Roxane Laboratories, Inc. was joined as a party via a Motion for Joinder in IPR2016-01102.

Pursuant to 37 C.F.R. § 42.63(e), Petitioners Par Pharmaceutical, Inc. *et al.*

respectfully submit the following current exhibit list.

Exhibit	Description
1001	U.S. Patent No. 5,665,772 (“the ’772 Patent”)
1002	File History for the ’772 Patent
1003	Declaration of William L. Jorgensen, Ph.D. in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 5,665,772
1004	Curriculum Vitae of William L. Jorgensen
1005	Randall Ellis Morris, <i>Rapamycins: Antifungal, Antitumor, Antiproliferative, and Immunosuppressive Macrolides</i> , 6 TRANSPLANTATION REVIEWS 39 (1992) (“Morris”)
1006	Gregory D. Van Duyne <i>et al.</i> , <i>Atomic Structure of the Rapamycin Human Immunophilin FKBP-12 Complex</i> , 113 J. AM. CHEMICAL SOC’Y 7433 (1991) (“Van Duyne”)
1007	Samuel H. Yalkowsky, <i>Estimation of Entropies of Fusion of Organic Compounds</i> , 18 INDUS. & ENG’G CHEMISTRY FUNDAMENTALS 108 (1979) (“Yalkowsky”)
1008	Thomas L. Lemke, <i>Chapter 16: Predicting Water Solubility</i> , REVIEW OF ORGANIC FUNCTIONAL GROUPS 113 (2d ed. 1988)
1009	U.S. Patent No. 5,233,036 (“Hughes”)
1010	U.S. Patent No. 4,650,803 (“Stella”)
1011	U.S. Patent No. 5,100,883 (“Scheihser”)
1012	Stuart L. Schreiber, <i>Chemistry and Biology of the Immunophilins and Their Immunosuppressive Ligands</i> , 251 SCI. 283 (1991) (“Schreiber”)
1013	Joseph B. Moon & W. Jeffrey Howe, <i>Computer Design of Bioactive Molecules: A Method for Receptor-Based de Novo Ligand Design</i> , 11 PROTEINS: STRUCTURE, FUNCTION, & GENETICS 314 (1991) (“Moon”)

Exhibit	Description
1014	Hans-Joachim Böhm, <i>LUDI: rule-based automatic design of new substituents for enzyme inhibitor leads</i> , 6 J. COMPUTER-AIDED MOLECULAR DESIGN 593 (1992) (“Böhm”)
1015	Silverman, <i>Chapter 2: Drug Discovery, Design, and Development</i> , THE ORGANIC CHEMISTRY OF DRUG DESIGN & ACTION 4 (1992) (“Silverman”)
1016	Julianto Pranata & William L. Jorgensen, <i>Computational Studies on FK506: Conformational Search and Molecular Dynamics Simulation in Water</i> , 113 J. AM. CHEMICAL SOC’Y 9483 (1991)
1017	William L. Jorgensen, <i>Rusting of the Lock and Key Model for Protein-Ligand Binding</i> , 254 SCI. 954 (1991)
1018	Modesto Orozco <i>et al.</i> , <i>Mechanism for the Rotamase Activity of FK506 Binding Protein from Molecular Dynamics Simulations</i> , 32 BIOCHEMISTRY 12864 (1993)
1019	Michelle L. Lamb & William L. Jorgensen, <i>Investigations of Neurotrophic Inhibitors of FK506 Binding Protein via Monte Carlo Simulations</i> , 41 J. MED. CHEMISTRY 3928 (1998)
1020	Michelle L. Lamb <i>et al.</i> , <i>Estimation of Binding Affinities of FKBP12 Inhibitors Using a Linear Response Method</i> , 7 BIOORGANIC & MEDICINAL CHEMISTRY 851 (1999)
1021	Thomas W. Bell, <i>Construction of a Soluble Heptacyclic Terpyridine</i> , 51 J. ORGANIC CHEMISTRY 764 (1986) (“Bell”)
1022	M. Ballauff, <i>Phase Equilibria in Rodlike Systems with Flexible Side Chains</i> , 19 MACROMOLECULES 1366 (1986) (“Ballauff”)
1023	R. Stern <i>et al.</i> , <i>Rigid rod polymers with flexible side chains</i> , 32 POLYMER 2096 (1991) (“Stern”)
1024	Michael G. Rossmann <i>et al.</i> , <i>Three-Dimensional Coordinates from Stereodiagrams of Molecular Structures</i> , B36 ACTA CRYSTALLOGRAPHICA 819 (1980) (“Rossmann”)

Exhibit	Description
1025	William L. Jorgensen & Julian Tirado-Rives, <i>The OPLS Potential Functions for Proteins. Energy Minimizations for Crystals of Cyclic Peptides and Crambin</i> , 110 J. AM. CHEMICAL SOC'Y 1657 (1988)
1026	Julian Tirado-Rives & William L. Jorgensen, <i>Molecular Dynamics of Proteins with the OPLS Potential Functions. Simulation of the Third Domain of Silver Pheasant Ovomuroid in Water</i> , 112 J. AM. CHEMICAL Soc'Y 2773 (1990)
1027	Michael L. Connolly, <i>Solvent-Accessible Surfaces of Proteins and Nucleic Acids</i> , 221 SCI. 709 (1983)
1028	Yoshihiko Nisibata <i>et al.</i> , <i>Automatic Creation of Drug Candidate Structures Based on Receptor Structure. Starting Point for Artificial Lead Generation.</i> , 47 TETRAHEDRON 8985 (1991)
1029	Stephen W. Michnick <i>et al.</i> , <i>Solution Structure of FKBP, a Rotamase Enzyme and Receptor for FK506 and Rapamycin</i> , 252 SCI. 836 (1991)
1030 ²	Declaration of Scott Bennett, Ph.D.
1031	Transcript of June 1, 2016 Conference Call
1032	Transcript of June 17, 2016 Conference Call
1033	Transcript of November 8, 2016 Conference Call
1034	Heinz-Herbert Fiebig <i>et al.</i> , <i>In Vitro and In Vivo Evaluation of US-NCI Compounds in Human Tumor Xenografts</i> , 17 CANCER TREATMENT REVS. 109 (1990)
1035	Transcript of the November 11, 2016 deposition of Howard A. Burris, III
1036	Robert C. Young <i>et al.</i> , <i>The Anthracycline Antineoplastic Drugs</i> , 305 NEW ENG. J. MED. 139 (1981)

² Ex. 1030 was served, but not filed, on May 27, 2016.

Exhibit	Description
1037	S. K. Carter <i>The Clinical Evaluation of Analogs – III. Anthracyclines</i> , 4 CANCER CHEMOTHERAPY PHARMACOLOGY 5 (1980)
1038	Harinder S. Garewal et al., <i>Phase I Trial of Esorubicin (4'-Deoxydoxorubicin)</i> , 2. J. CLINICAL ONCOLOGY 1034 (1984)
1039	Elaine M. Rankin et al., <i>A Phase II Study of 4-Deoxydoxorubicin in Advanced Breast Cancer</i> , 23 EUR. J. CANCER CLINICAL ONCOLOGY 1979 (1987)
1040	Thomas P. Miller et al., <i>Activity of Esorubicin in Recurrent Malignant Lymphoma: A Southwest Oncology Group Study</i> , 9 J. CLINICAL ONCOLOGY 1204 (1991)
1041	S. T. Crooke et al., <i>Structure-Activity Relationships of Anthracyclines Relative to Effects on Macromolecular Syntheses</i> , 14 MOLECULAR PHARMACOLOGY 290 (1978)
1042	Toshikazu Oki et al., <i>New Antitumor Antibiotics, Aclacinomycins A and B</i> , 28 J. ANTIBIOTICS 830 (1975)
1043	Vivien H. Bramwell et al., <i>Carminomycin vs Adriamycin in Advanced Soft Tissue Sarcomas: an EORTC Randomised Phase II Study</i> , 19 EUR. J. CANCER CLINICAL ONCOLOGY 1097 (1983)
1044	European Soc'y for Med. Oncology & Anticancer Fund, <i>Stomach Cancer: A Guide for Patients</i> (2012), https://www.esmo.org/content/download/6635/115239/file/EN-Stomach-Cancer-Guide-for-Patients.pdf
1045	Nat'l Comprehensive Cancer Network, <i>Clinical Practice Guidelines in Oncology (NCCN Guidelines): Gastric Cancer – Version 3.2016</i> (2016)
1046	British Columbia Cancer Agency, <i>Drug Manual - Epirubicin</i> (Jan. 1, 2015), http://www.bccancer.bc.ca/drug-database-site/Drug%20Index/Epirubicin_monograph_1Jan2015.pdf

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