UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC. ,
Patent Owners.

U.S. Patent No. 9,326,945 to Patel *et al.*

Inter Partes Review IPR2018-00892

PETITIONER MYLAN PHARMACEUTICALS INC.'S UPDATED LIST OF EXHIBITS

LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,326,945
1002	Declaration of Dr. Park
1003	Prosecution History of U.S. Patent No. 9,326,945
1004	Carreiro et al., "Apixaban, an oral direct Factor Xa inhibitor: awaiting the verdict," *Expert Opin. Investig. Drugs*, 17(12):1937-1945 (2008)
1005	Pinto et al., "Discovery of 1-(4-methoxyphenyl)-7-oxo-6-(4-(2-oxopiperidin-1-yl)phenyl)-4,5,6,7-tetrahdyro-1H-pyrazolo[3,4-c]pyridine-3-carboxamide (Apixaban, BMS-562247), a highly potent, selective, efficacious, and orally bioavailable inhibitor of blood coagulation Factor Xa," *J. Med. Chem.*, 50:5339-5356 (2007)
1006	International Patent Publication WO 2010/147978 to Nause
1007	U.S. Patent No. 6,967,208 to Pinto et al.
1008	U.S. Patent Publication No. 2006/0160841 to Wei et al.
1009	Ashford, "Bioavailability: physicochemical and dosage form factors," in *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*, 3rd ed., M. E. Aulton, ed., Churchill Livingstone Elsevier, pp. 286-291, 443-449 (2007)
1010	Rudnic et al., "Tablet Dosage Forms," in *Modern Pharmaceutics*, 4th ed., G.S. Banker and C.T. Rhodes, eds., Taylor & Francis Group, Boca Raton, FL, pp. 333-359 (2002)
1011	Stegemann, "When poor solubility becomes an issue: from early stage to proof of concept," *Eur. J. Sci*., 31(5):249-261 (2007)
1012	International Patent Publication WO 2010/003811 to Hafner et al.

Exhibit No.	Description
1013	Augsburger et al., "Tablet Formulation," in *Encyclopedia of Pharmaceutical Technology*, 2nd ed., Swarbrick et al., eds., pp. 2701-2712 (2002)
1014	U.S. Patent No. 5,314,506
1015	Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) (Aug. 1997)
1016	United States Pharmacopeia, 27th ed., General Notices and Requirements, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 11-12 (2004)
1017	U.S. Provisional Application No. 61/308,056
1018	The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism, U.S. Department of Health and Human Services (2008)
1019	Beckman, M.G., "Venous thromboembolism: a public health concern," Am. J. Prev. Med., 38(4s):S495-S501 (2010)
1020	Cohen, "Venous thromboembolism (VTE) in Europe. The number of VTE events and associated morbidity and mortality," *Thromb. Haemost*., 98(4):756-764 (2007)
1021	Remko, "Molecular structure, lipophilicity, solubility, absorption, and polar surface area of novel anticoagulant agents", *J. Mol. Structure*, 916:76-85 (2009)
1022	Ungell et al., "Biopharmaceutical Support in Candidate Drug Selection," in *Pharmaceutical Preformulation and Formulation*, M. Gibson, ed., 2nd Informa Healthcare, pp. 97-153 (2004)

Exhibit No.	Description
1023	W-Q Tong., "Practical aspects of solubility determination in pharmaceutical preformulation, in Solvent Systems and Their Selection," in *Pharmaceutics and Biopharmaceutics*, P. Augustijns and M. Brewster (eds.), Springer, New York, pp. 137-149 (2007)
1024	Yu et al., "Biopharmaceutics classification system: the scientific basisf for biowaiver extensions," *Pharm Res*., 19(7): 921-925, (2002)
1025	Brown, C.K., "Dissolution method development: an industry perspective," in *Pharmaceutical Dissolution Testing*, J. Dressman and J. Krämer (eds.), Taylor & Francis, New York, pp. 351-372 (2005)
1026	Gong et al., "Principles of solubility," in *Solvent Systems and Their Selection in Pharmaceutics and Biopharmaceutics*," P. Augustijns and M. Brewster (eds.), Springer, New York, pp. 1-27 (2007)
1027	United States Pharmacopeia XX, 20th Revision, Description and solubility, United States Pharmacopeil Convention, Inc., Rockville, MD, p. 1121 (1980)
1028	Diebold, S.M., "Physiological parameters relevant to dissolution testing: hydrodynamic considerations," in *Pharmaceutical Dissolution Testing*, J. Dressman and J. Kramer (eds.), Taylor & Francis, New York, pp. 127-191 (2005)
1029	Dahan et al., "Prediction of solubility and permeability class membership: Provisional BCS classification of the world's top oral drugs," *AAPS J*., 11(4):740-746 (2009)
1030	Shah, V.P., "The role of dissolution testing in the regulation of pharmaceuticals. The FDA perspective." in Pharmaceutical Dissolution Testing, J. Dressman and J. Krämer (eds.), Taylor & Francis, New York, pp. 81-96 (2005)

Exhibit No.	Description
1031	Dressman, "The BCS: Where do we go from here?," *Pharma. Tech*., 68-76 (2001)
1032	Krämer, J. et al., "Dissolution method development with a view to quality control," in Pharmaceutical Dissolution Testing, J. Dressman and J. Krämer (eds.), Taylor & Francis, New York, pp. 1-37 (2005)
1033	*Handbook of Pharmaceutical Excipients*, 6th ed., R. Rowe, P. Shesky, and M.E. Quinn (eds.), Pharmaceutical Press, Grayslake, IL, pp. 1-888 at p. 651 (2009)
1034	Hom et al., "Oral dosage form design and its influence in dissolution rates for a series of drugs," *J. Pharm. Sci.*, 59(6): 827-830 (1970)
1035	Remington's Pharmaceutical Sciences, 18th ed., A.R. Gennaro (ed.), Mack Publishing Co., Easton, PA, pp. 1615-1632 (1990)
1036	Transcript of August 30, 2018 Telephonic Hearing in IPR2018-00892
1037	Declaration of James L. Mullins, Ph.D. and Attachments
1038	Supplemental Declaration of Kinam Park, Ph.D.
1039	Carreiro publication from Taylor and Francis Online website, available at https://www.tandfonline.com/doi/full/10.1517/13543780802528625
1040	Carreiro publication from Expert Opinion on Investigational Drugs obtained from National Library of Medicine
1041	Federal Register, Vol. 62, No. 164 (Aug.25, 1997) at 44974-44975
1042	Rudnic publication from Modern Pharmaceutics, Third Edition
1043	Rudnic publication from Modern Pharmaceutics, Fourth Edition
1044	Second Supplemental Declaration of Kinam Park, Ph.D.

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