Paper No. 4

Filed on behalf of: Mylan Pharmaceuticals Inc.

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY

and

PFIZER INC.,
Patent Owner.

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Case IPR2018-00892
Patent 9,326,945 B2

Paper No. 4 Served and Filed: April 20, 2018

**CORRECTED EXHIBIT LIST AND NOTICE THEREOF**

In response to the "NOTICE OF FILING DATE ACCORDED TO PETITION AND TIME FOR FILING PATENT OWNER PRELIMINARY RESPONSE" dated April 19, 2018 (Paper No. 3) in the above-referenced IPR2018-00892, and the comments made therein, Petitioner has filed herewith a corrected Appendix B: Listing of Exhibits which accurately reflects the exhibits and corresponding exhibits numbers filed with Petitioner's Petition (Paper No. 2) in compliance with 37 C.F.R. § 42.63(e).

Respectfully submitted,

/ Robert L. Florence /
Robert L. Florence, Lead Counsel
Registration No. 54,933

## APPENDIX B:LISTING 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) |

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