IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mylan Pharmaceuticals Inc., Petitioner

v.

Nissan Chemical Industries Ltd.
Patent Owner

U.S. Patent No. 5,856,336 to Fujikawa *et al.* Issue Date: January 5, 1999
Title: Quinoline Type Mevalonolactones

Inter Partes Review No.: <u>IPR2015-01069</u>

Petitioners Exhibit List



Petitioner's Exhibit List

| Exhibit # | Description |
|--------------|--|
| 1001 | U.S. Patent No. 5,856,336 ("the '336 patent") |
| 1002 | U.S. Patent No. 5,872,130 |
| 1003 | U.S. Application Ser. No. 233,752 |
| 1004 | Japanese Patent Application No. JP 62-207224 with English translation provided by the '336 patentee from U.S. Application Ser. 07/233,752, related family member of the '336 patent, with accompanying sworn declaration provided by the patentee to the USPTO attesting to the accuracy of the translation. |
| 1005 | Japanese Patent Application No. JP 63-15585 with English translation provided by the '336 patentee from U.S. Application Ser. 07/233,752, related family member of the '336 patent, with accompanying sworn declaration provided by the patentee to the USPTO attesting to the accuracy of the translation. |
| 1006 | Japanese Patent Application No. JP 63-193606 with English translation provided by the '336 patentee from U.S. Application Ser. 07/233,752, related family member of the '336 patent, with accompanying sworn declaration provided by the patentee to the USPTO attesting to the accuracy of the translation. |
| 1007 | Curriculum Vitae of Roger Frank Newton, Ph.D. |
| 1008 | Declaration of Roger Frank Newton, Ph.D. |
| 1009 | Faizulla G. Kathawala, et al., <i>XU 62-320, An HMG-CoA Reductase Inhibitor, More Potent Than Compactin</i> , Abstract for American Chemical Society library stamp July 29, 1987 |
| 1010 | U.S. Patent No. 4,739,073 |

Alston & Bird LLP



| Exhibit # | Description |
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| 1011 | R. G. Engstrom et al., <i>Hypolipoproteinemic Effects of a Potent HMG-CoA Reductase Inhibitor</i> , IX International Symposium on Drugs Affecting Lipid Metabolism, Florence (Italy), Oct. 22-25, 1986 |
| 1012 | Jonathan A. Tobert, New Developments in Lipid-Lowering Therapy: The Role of Inhibitors of Hydroxymethylglutaryl-Coenzyme A Reductase, 76 CIRCULATION 534 (1987) |
| 1013 | Ta-Jyh Lee, Synthesis, SARs and Therapeutic Potential of HMG-CoA Reductase Inhibitors, 8 TRENDS PHARMACOL. SCI. 442 (1987) |
| 1014 | Akira Endo et al., <i>ML-236A</i> , <i>ML-236B</i> , and <i>ML-236C</i> , <i>New Inhibitors of Cholesterogenesis Produced by Penicillium Citrinium</i> , 29 J. ANTIBIOTICS 1346 (1976) |
| 1015 | Declaration of David Gortler, Pharm.D. |
| 1016 | U.S. Patent No. 4,647,576 |
| 1017 | Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), FOOD AND DRUG ADMINISTRATION, listing for active ingredient "lovastatin," <i>available at</i> http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?A ppl_No=019643&TABLE1=OB_Disc (last visited April 13, 2015) |
| 1018 | U.S. Patent No. 4,613,610 |
| 1019 | U.S. Patent No. 4,681,893 |
| 1020 | U.S. Patent No. 4,751,235 |
| 1021 | U.S. Patent No. 4,761,419 |
| 1022 | Alfred W. Alberts, Mevinolin: A Highly Potent Competitive Inhibitor of Hydroxymethylglutaryl-Coenzyme a Reductase and a Cholesterol-Lowering Agent, 77 PROC. NAT'L. ACAD. SCI. U.S.A. 3957 (1980) |

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| 1023 | J.B. Taylor & P.D. Kennewell, Introductory Medicinal Chemistry 94 (1981) |
| 1024 | Corwin Hansch et al., "Aromatic" Substituent Constants for Structure-Activity Correlations, 16 J. MED. CHEM. 1207 (1973) ("Hansch II") |
| 1025 | European Patent No. 0114027 |
| 1026 | U.S. Patent No. 4,537,859 |
| 1027 | Stephen M. Berge, <i>Pharmaceutical Salts</i> , 66 J. PHARM. SCI. 1 (1977) |
| 1028 | Philip L. Gould, Salt Selection for Basic Drugs, 33 Int. J. Pharm. 201 (1986) |
| 1029 | John T. Suh et al., Angiotensin-Converting Enzyme Inhibitors New Orally Active Antihypertensive (Mercaptoalkanoyl)- and [(Acylthio)alkanoyl]glycine Derivatives, 28 J. MED. CHEM. 57 (1985) |
| 1030 | Michael S. Brown, M.D. et al., Lowering Plasma Cholesterol by Raising LDL Receptors, 305 New Eng. J. Med. 515 (1981) |
| 1031 | Fujikawa Reply to the Opposition to Fujikawa et al.'s Motion to Add Counts 3 and 4, received July 21, 1992. U.S. Interference No. 102,608 ("Paper No. 32") |
| 1032 | Declaration of Masaki Kitahara, submitted in the '336 patent, dated May 25, 1992 |
| 1033 | O. E. Schultz et al., Schätzung des Verteilungfkoeffizienten mit Hilfe Quantenchemischer Molekülgroβen, 25 ZEITSCHRIFT FÜR NATURFORSCHUNG B 1024 (1970), certified English translation included |



| Exhibit # | Description |
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| 1034 | Corwin Hansch et al., The Effect of Intramolecular Hydrophobic Bonding on Partition Coefficients, 32 J. Org. Chem. 2583 (1967) ("Hansch I") |
| 1035 | European Patent Publication 179,559 |
| 1036 | I. T. Scoular et al., Human Studies on the Bioavailability of a Quaternary Ammonium Compound, Tiemonium Iodide and Tiemonium Methosulphate, 4 Curr. Med. Res. Opin. 732 (1977) |
| 1037 | Curriculum Vitae of David Gortler, Pharm.D. |
| 1038 | David J. Shapiro & Victor W. Rodwell, Regulation of Hepatic 3- Hydroxy-3-Methylglutaryl Coenzyme A Reductase and Cholesterol Synthesis, 246 J. BIOL. CHEM. 3210 (1971) |
| 1039 | Yoshio Tsujita et al., CS-514, A Competitive Inhibitor of 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase: Tissue-Selective Inhibition of Sterol Synthesis and Hypolipidemic Effect on Various Animal Species, 877 BIOCHIMICA ET BIOPHYSICA ACTA 50 (1986) |
| 1040 | G.E. Stokker et al., 3-Hydroxy-3-Methylglutaryl-Coenzyme A Reductase Inhibitors. 1. Structural Modification of 5-Substituted 3,5-Dihydroxypentanoic Acids and Their Lactone Derivatives, 28 J. Med. Chem. 347 (1985) ("Stokker I") |
| 1041 | G.E. Stokker et al., 3-Hydroxy-3-Methylglutaryl-Coenzyme A Reductase Inhibitors 3. 7-(3,5-Disubstituted [1,1'-biphenyl]-2-yl)-3,5-Dihydroxy-6-Heptenoic Acids and Their Lactone Derivatives, 29 J. Med. Chem. 170, 175 (1986) ("Stokker II") |
| 1042 | Final Hearing, November 22, 1994. U.S. Interference No. 102,608 ("Paper No. 122") |