

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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HIKMA PHARMACEUTICALS USA INC.,  
HIKMA PHARMACEUTICALS PLC,  
Petitioner,

v.

AMARIN PHARMACEUTICALS IRELAND LIMITED,  
Patent Owner.

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Case IPR2021-00215  
Patent 8,642,077 B2  
Issued: February 4, 2014

Title: STABLE PHARMACEUTICAL  
COMPOSITION AND METHODS OF USING SAME

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**DECLARATION OF EDWARD A. FISHER, M.D., Ph.D., M.P.H.**

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## LIST OF CITED EXHIBITS

No.	Description
1001	U.S. Patent No. 8,642,077 B2 to Manku et al. (the “’077 patent”)
1002	Expert Declaration of Edward A. Fisher, M.D., Ph.D., M.P.H.
1003	WO 2007/142118 to Yokoyama et al. (2007) (certified English translation) (“Yokoyama I”)
1004	Trevor A. Mori et al., <i>Purified Eicosapentaenoic and Docosahexaenoic Acids Have Differential Effects on Serum Lipids and Lipoproteins, LDL Particle Size, Glucose, and Insulin in Mildly Hyperlipidemic Men</i> , 71 AM. J. CLINICAL NUTRI. 1085 (2000) (“Mori”)
1005	Mitsuhiro Yokoyama et al., <i>Effects of Eicosapentaenoic Acid on Major Coronary Events in Hypercholesterolaemic Patients (JELIS): a Randomized Open- Label, Blinded Endpoint Analysis</i> , 369 LANCET 1090 (2007) (“Yokoyama II”)
1006	Noriko Satoh et al., <i>Purified Eicosapentaenoic Acid Reduces Small Dense LDL, Remnant Lipoprotein Particles, and C-Reactive Protein in Metabolic Syndrome</i> , 30 DIABETES CARE 144 (2007) (“Satoh”)
1007	Sameline Grimsgaard et al., <i>Highly Purified Eicosapentaenoic Acid and Docosahexaenoic Acid in Humans Have Similar Triacylglycerol-Lowering Effects but Divergent Effects on Serum Fatty Acids</i> , 66 AM. J. CLINICAL NUTRI. 649 (1997) (“Grimsgaard”)
1008	<i>Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report</i> , 106 CIRCULATION 3143 (2002) (“ATP-III”)
1009	Plaintiffs’ Corrected Post-Trial Proposed Findings of Fact and Conclusions of Law (Feb. 27, 2020) from <i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 16-2525, D.I. 377, ¶ 510 (D. Nev.) (“Amarin FFCL”)
1010	Day 2 (Jan. 14, 2020) Trial Transcript from <i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 16-2525 (D. Nev.) (Testimony of Dr. Budoff) (“Budoff Tr.”)
1011	Margaret Carroll, et al., <i>Serum Lipids of Adults 20–74 Years: United States, 1976–80</i> , Nat’l Ctr for Health Statistics, Vital & Health Statistics, 11(242) (1993) (“Nat’l Health Survey”)

No.	Description
1012	Hartmut H-J Schmidt et al., <i>Lipid Evaluation in HIV-1-Positive Patients Treated with Protease Inhibitors</i> , 4 ANTIVIRAL THER. 163 (1999) (“Schmidt”)
1014	Lovaza®, PHYSICIANS’ DESK REFERENCE 2699 (62d ed. 2007) (“Lovaza PDR”)
1015	Shuichi Nozaki et al., <i>Effects of Purified Eicosapentaenoic Acid Ethyl Ester on Plasma Lipoproteins in Primary Hypercholesterolemia</i> , 62 INT’L J. VITAMIN & NUTR. RES. 256(1992) (“Nozaki”)
1016	Koji Shinozaki et al., <i>The Long-Term Effect of Eicosapentaenoic Acid on Serum Levels of Lipoprotein (a) and Lipids in Patients with Vascular Disease</i> , 2(2) J. ATHEROSCL. THROMB. 107 (1996) (“Shinozaki”)
1018	Day 7 (Jan. 28, 2020) Trial Transcript from <i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 16-2525 (D. Nev.) (Testimony of Dr. Toth) (“Toth Tr.”)
1019	Plaintiffs’ Validity Contentions from <i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 16-2525 (D. Nev.)
1020	Plaintiffs’ Infringement Contentions from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630 (D. Del.)
1021	Plaintiffs’ Opposition to Motion to Dismiss from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630 (D. Del.)
1022	Plaintiffs’ First Amended Complaint from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630, D.I. 17 (D. Del.) (“Complaint”)
1023	Exhibit U to Plaintiffs’ First Amended Complaint from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630, D.I. 17-22 (D. Del.) (Christie Ballantyne et al., <i>Efficacy and Safety of Eicosapentaenoic Acid Ethyl Ester (AMR101) Therapy in Statin-Treated Patients with Persistent High Triglycerides</i> , AM. J. CARDIOL. 1 (2012)) (“Ballantyne”)
1024	Exhibit V to Plaintiffs’ First Amended Complaint from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630, D.I. 17-23 (D. Del.) (Deepak L. Bhatt et al., <i>Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia</i> , 380 N. ENGL. J. MED. 11 (2018)) (“Bhatt”)

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