

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AMARIN PHARMACEUTICALS IRELAND LIMITED,
Patent Owner.

Case IPR2022-00215
Patent 8,642,077 B2

**JOINT MOTION TO TERMINATE
UNDER 35 U.S.C. § 317**

PETITIONER'S UPDATED EXHIBIT LIST

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”)

No.	Description
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”)
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”)
1013	Expert Declaration of Sylvia Hall-Ellis, Ph.D.
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”)
1017	Joint Stipulations of Fact from <i>Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.</i> , No. 16-2525, D.I. 324 (D. Nev.)
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.)

No.	Description
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")
1025	Amarin Response to U.S. Patent Office re U.S. Patent Application No. 13/768,906 (Aug. 26, 2013)
1026	Michael H. Davidson et al., <i>Efficacy and Tolerability of Adding Prescription Omega-3 Fatty Acids 4 g/d to Simvastatin 40 mg/d in Hypertriglyceridemic Patients: An 8-Week, Randomized, Double-Blind, Placebo-Controlled Study</i> , 29 Clin. Therapeutics 1354 (2007) ("Davidson")
1027	Yasushi Saito et al., <i>Effects of EPA on Coronary Artery Disease in Hypercholesterolemic Patients with Multiple Risk Factors: Sub-Analysis of Primary Prevention Cases from the Japan EPA Lipid Intervention Study (JELIS)</i> , 200 Atherosclerosis 135 (2008) ("Saito")
1028	Notice of Allowability from U.S. Patent Office re U.S. Patent Application No. 13/768,906 (Sept. 30, 2013)

No.	Description
1029	FDA Briefing Document, Endocrinologic and Metabolic Drugs, Advisory Committee Meeting regarding ANCHOR trial (Oct. 16, 2013)
1030	U.S. Patent Office Interview Summary re U.S. Patent Application No. 13/614,111 (Dec. 12, 2012)
1031	Amarin Supplemental Response to U.S. Patent Office re U.S. Patent Application No. 13/614,111 (Jan. 11, 2013)
1032	Notice of Allowability from U.S. Patent Office re U.S. Patent Application No. 13/614,111 (Feb. 11, 2013)
1033	Vascepa® Label (rev. Dec. 2019)
1034	World Health Organization Memorandum, <i>Classification of Hyperlipoproteinemias and Hyperlipoproteinemias</i> , 43 Circulation 501 (1972) (“WHO Memo”)
1035	Declaration of C. Rosebraugh from <i>Amarin Pharma, Inc. et al. v. U.S. F.D.A. et al.</i> , No. 15-3588, D.I. 54 (S.D.N.Y.)
1036	Scheduling Order from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630, D.I. 50 (D. Del.)
1037	Hikma’s Motion to Dismiss from <i>Amarin Pharma, Inc. et al. v. Hikma Pharm. USA Inc. et al.</i> , C.A. No. 20-1630, D.I. 19 (D. Del.)
1038	Office Action from U.S. Patent Office re U.S. Patent Application No. 13/768,906 (May 24, 2013)
1039	Original Japanese version of WO 2007/142118 to Yokoyama et al.
1040	U.S. Patent No. 6,384,077 to Peet et al.
1041	U.S. Patent No. 6,479,544 to Horrobin
1042	U.S. Patent No. 7,119,118 to Peet et al.
1043	Amarin Reports Fourth Quarter and Full Year 2004 Results Report

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