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Filed on Behalf Of:

Novartis Pharmaceuticals Corporation

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN AND
UNIVERSITY OF SOUTH FLORIDA,
Patent Owners.

Case IPR2023-01346
U.S. Patent No. 10,633,344

NOVARTIS'S UPDATED EXHIBIT LIST

Exhibit	Description	Abbreviation
1001	U.S. Patent No. 10,633,344	’344 patent
1002	Declaration of Robin D. Rogers, Ph.D.	Rogers
1003	Declaration of Leah Appel, Ph.D.	Appel
1004	Hickey et al., *Performance comparison of a co-crystal of carbamazepine with marketed product,* 67 Eur. J. Pharm. & Biopharm. 112–19 (2007)	Hickey
1005	U.S. Patent No. 7,927,613	Almarsson
1006	MARTINDALE: THE COMPLETE DRUG REFERENCE, at v-x (preface), 514–20 (entry for carbamazepine), 2242 (entry for saccharin) (37th ed. 2011)	Martindale 2011
1007	Ueto et al., *Polymorphs and a Hydrate of Furosemide−Nicotinamide 1:1 Cocrystal,* 12 Crys. Growth & Des. 485–94 (2012)	Ueto
1008	[Intentionally Blank]	
1009	U.S. Pat. Pub. 2003/0224006 (published ’956 priority application)	’006 Publication
1010	REMINGTON: ESSENTIALS OF PHARMACEUTICS, at 177–206 (Chapter 11: Molecular Structure, Properties, and States of Matter), 581–610 (Chapter 30: Oral Solid Dosage Forms) (22nd ed. 2012)	Remington 2012
1011	[Intentionally Blank]	
1012	[Intentionally Blank]	
1013	[Intentionally Blank]	
1014	U.S. Application No. 60/360,768	’768 application
1015	U.S. Application No. 10/378,956	’956 application
1016	Prosecution History of U.S. Patent 10,633,344 (foreign references removed)	’344 patent prosecution history
1017	Prosecution History of U.S. Patent Application No. 10/378,956 (foreign references removed)	’956 application prosecution history

Exhibit	Description	Abbreviation
1018	Joint Claim Construction & Prehearing Statement and Exhibit A (dated June 6, 2023); 3:22-cv-04913-AMO, D.I. 73	Joint Claim Construction & Prehearing Statement
1019	Plaintiffs' Opening Claim Construction Brief (dated August 1, 2023); 3:22-cv-04913-AMO, D.I. 77	Plaintiffs' Claim Construction Brief
1020	Transcript of July 11, 2023 Deposition of Scott L. Childs, Ph.D., with errata, at 18, 27	Childs Dep. Tr.
1021	U.S. Patent Application No. 15/639,223	'223 application
1022	Prosecution History of U.S. Patent Application No. 15/639,223 (foreign references removed)	'223 prosecution history
1023	Prosecution History of U.S. Patent No. 7,927,613 (Almarsson) (U.S. Patent Application No. 10/660,202) (foreign references removed)	Almarsson prosecution history
1024	Desiraju, *Chemistry beyond the molecule*, 412 Nature 397–400 (2001)	Desiraju 2001
1025	Aakeröy et al., *Do Polymorphic Compounds Make Good Cocrystallizing Agents? A Structural Case Study that Demonstrates the Importance of Synthon Flexibility,* 3 Crys. Growth & Des. 159–165 (2003)	Aakeröy 2003
1026	Dunitz, *Are crystal structures predictable?*, 5 Chem. Commun. 545–48 (2003)	Dunitz
1027	Reddy et al., *Phenyl-Perfluorophenyl Synthon Mediated Cocrystallization of Carboxylic Acids and Amides,* 4 Crys. Growth & Des. 89–94 (2004)	Reddy
1028	Fleischman et al., *Crystal Engineering of the Composition of Pharmaceutical Phases: Multiple-Component Crystalline Solids Involving Carbamazepine,* 3 Crys. Growth & Des. 909–19 (2003)	Fleischman
1029	Aitipamula et al., *Polymorphs and Solvates of a Cocrystal Involving an Analgesic Drug, Ethenzamide, and 3,5-Dinitrobenzoic Acid,* 10 Crys. Growth & Des. 2229–38 (2010)	Aitapamula
1030	Guillory, Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, *in* POLYMORPHISM IN PHARMACEUTICAL SOLIDS, at 183–226 (1999)	Guillory

Exhibit	Description	Abbreviation
1031	21 C.F.R. § 184 (2000)	21 C.F.R. § 184 (2000)
1032	Moss et al., *Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure (IUPAC Recommendations 1995),* 67 Pure & Appl. Chem. 1307–75, at 1307–10, 1316, 1341 (1995)	Moss
1033	Leigh et al., PRINCIPLES OF CHEMICAL NOMENCLATURE: A GUIDE TO IUPAC RECOMMENDATIONS 14, 85 (1998)	IUPAC 1998
1034	Gavezzotti, *Are Crystal Structures Predictable?*, 27 Acc. Chem. Res. 309–14 (1994)	Gavezzotti
1035	PHYSICIANS' DESK REFERENCE, at 1048–52 (entry for Coumadin®), 1427–31 (entry for Amoxil®), 2665–68 (entry for Vibramycin® Hyclate) (58th ed. 2004)	PDR 2004
1036	Hilton & Deasy, *Use of Hydroxypropyl Methylcellulose Acetate Succinate in an Enteric Polymer Matrix To Design Controlled-Release Tablets of Amoxicillin Trihydrate,* 82 J. Pharm. Scis. 737–43 (1993)	Hilton
1037	Coumadin® Label (Revised October 2011)	Coumadin® Label
1038	Vibramycin® Label (Revised December 2022)	Vibramycin® Label
1039	Amoxil® Label (Revised September 2015)	Amoxil® Label
1040	MARTINDALE: THE COMPLETE DRUG REFERENCE, at vii-viii (preface) (32nd ed. 1999)	Martindale 1999
1041	REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, at xiii–xiv (preface), 1615–49 (Chapter 92: Oral Solid Dosage Forms) (19th ed. 1995)	Remington 1995
1042	MERRIAM WEBSTER'S MEDICAL DICTIONARY, at 98 (1995)	Webster's Medical Dictionary
1043	Kibbe, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, at x-xii (preface), 129–33 (entry for cellulose, microcrystalline), 359–61, 364–69 (entry for lactose), 685–91 (entry for starch) (6th ed. 2009)	Handbook of Pharmaceutical Excipients
1044	U.S. Patent No. 2,777,859	'859 patent
1045	U.S. Patent No. 7,807,196	'196 patent
1046	Jung et al., *Bioavailability of indomethacin-saccharin cocrystals,* 62 J. Pharm. & Pharmacol. 1560–68 (2010)	Jung
1047	U.S. Patent No. 7,183,272	Aronhime

Exhibit	Description	Abbreviation
1048	Aakeröy, *Crystal Engineering: Strategies and Architectures,* B53 Acta Cryst. 569–86 (1997)	Aakeröy 1997
1049	THE MERCK INDEX, at v (foreword), 6–7 (entry 26, aceglutamide), 43 (entry 222, aldioxa), 49 (entry 254, allantoin), 70 (entry 396, amicoumacin A), 80–81 (entry 458, aminopentamide), 116 (entry 690, anthramycin), 147 (entry 863, atenolol), 205 (entry 1208, bidisomide), 234 (entry 1381, bromisovalum), 268–69 (entry 1599, buzepide), 298 (entry 1788, carbamazepine), 317–18 (entry 1886, carumonam), 326 (entry 1931, cefcapene pivoxil), 330 (entry 1947, cefotetan), 330–31 (entry 1949, cefoxitin), 333 (entry 1958, cefsulodin), 335 (entry 1966, cefuroxime), 337 (entry 1974, cellocidin), 340 (entry 1990, cephalonium), 341 (entry 1995, cephamycins), 379 (entry 2211, chlortetracycline), 413–14 (entry 2390, clocapramine), 495 (entry 2848, darifenacin), 507 (entry 2905, demeclocycline), 591–92 (entry 3395, disopyramide), 606–07 (entry 3474, doxycycline), 638 (entry 3631, enviomycin), 665 (entry 3766, ethenzamide), 887 (entry 4962, indecainide), 978 (entry 5482, levetiracetam), 1032 (entry 5801, meclocycline), 1095 (entry 6170, metopimazine), 1101 (entry 6199, micafungin), 1112 (entry 6249, modafinil), 1128 (entry 6329, muramyl dipeptide), 1205 (entry 6753, nosiheptide) & (entry 6755, novobiocin), 1242–43 (entry 7011, oxiracetam), 1249 (entry 7046, oxytetracycline), 1292 (entry 7280, phenacemide), 1297 (entry 7309, pheneturide), 1335 (entry 7535, pipamazine) & (entry 7536, pipamperone), 1342 (entry 7569, piracetam), 1344 (entry 7581, piritramide), 1391 (entry 7863, progabide), 1479 (entry 8319, ritipenem), 1501–02 (entry 8446, saquinavir), 1614 (entry 9135, taltirelin), 1630 (entry 9218, temozolomide), 1631 (entry 9221, tenidap), 1764 (entry 9967, valdetamide), 1766 (entry 9978, valnoctamide) & (entry 9980, valpromide), 1782 (entry 10062, viomycin) (13th ed. 2001)	2001 Merck Index
1050	Scheduling Order (dated January 18, 2023), Joint Stipulation and Order to Modify the Scheduling Order (dated January 24, 2023); 3:22-cv-04913-AMO, D.I. 55, 57	N.D. Cal. Scheduling Orders
1051	USPTO Assignment Database Entry for U.S. Patent No. 10,633,344, available at https://assignment.uspto.gov/patent/index.html#/patent/search/resultAbstract?id=10633344&type=patNum (accessed June 8, 2023)	USPTO Assignment Database Entry for ’344 patent

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1052	USPTO Assignment Database Entry for U.S. Patent Application No. 15/639,223, available at https://assignment.uspto.gov/patent/index.html#/patent/search/resultAbstract?id=15639223&type=applNum (accessed August 8, 2023)	USPTO Assignment Database Entry for ’223 application
1053	Curriculum Vitae of Robin D. Rogers, Ph.D.	Rogers CV
1054	Curriculum Vitae of Leah Appel, Ph.D.	Appel CV
1055	U.S. Patent No. 2,665,277	Homeyer
1056	U.S. Patent No. 3,664,858	Huffman
1057	U.S. Patent No. 5,023,092	DuRoss
1058	U.S. Patent No. 5,994,365	’365 patent
1059	U.S. Patent No. 6,559,293	’293 patent
1060	CA 1148020A1	McCoy
1061	GB 2169601	Jackson
1062	JP-B-46-33588 (UM00014569-71)	Sanzu
1063	Ammar & Omar, *Effect of Aromatic Hydrotropes on the Solubility of Carbamazepine. Part II: Effect of Nicotinamide, Sodium Salts of Benzoic, Naphthoic and Nicotinic Acids,* 35 Egypt J. Pharmaceut. Sci. 209–23 (1994)	Ammar
1064	Caira, *Molecular complexes of sulfonamides. 3. Structure of 5-methoxysulfadiazine (Form II) and its 1:1 complex with acetylsalicylic acid,* 24 J. Chem. Crystallogr. 695–701 (1994)	Caira
1065	Desiraju, *Supramolecular Synthons in Crystal Engineering—A New Organic Synthesis,* 34 Angew. Chem. Int’l Ed. Engl. 2311–27 (1995)	Desiraju 1995
1066	Freemont et al., *Cocrystal structure of an editing complex of Klenow fragment with DNA,* 85 Proc. Nat’l Acad. Sci. 8924–28 (1998)	Freemont
1067	Smith et al., *The utility of 4-aminobenzoic acid in promotion of hydrogen bonding in crystallization processes: the structures of the cocrystals with halo and nitro substituted*	Smith

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	aromatic compounds, and the crystal structures of the adducts with 4-nitroaniline (1:1), 4-(4-nitrobenzyl)pyridine (1:2), and (4-nitrophenyl)acetic acid (1:1), 27 J. Chem. Crystallogr. 307–17 (1997)	
1068	Vishweshwar et al., *Molecular Complexes of Homologous Alkanedicarboxylic Acids with Isonicotinamide: X-ray Crystal Structures, Hydrogen Bond Synthons, and Melting Point Alternation,* 3 Crys. Growth & Des. 783–90 (2003)	Vishweshwar
1069	"Carbamazepine," PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/Carbamazepine (accessed August 19, 2023)	PubChem Entry Carbamazepine
1070	"Saccharin," PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/5143 (accessed August 19, 2023)	PubChem Entry Saccharin
1071	21 C.F.R. § 180 (2013)	21 C.F.R. § 180 (2013)
1072	Reply Declaration of Robin D. Rogers, Ph.D.	Rogers Reply
1073	Fed. Reg. Vol. 67, No. 191, 61910-11 (Oct. 2, 2002)	67 Fed. Reg. 61910
1074	Osterberg & See, *Toxicity of Excipients—A Food and Drug Administration Perspective*, 22 Int'l J. Toxicology 377–80 (2003)	Osterberg
1075	MARTINDALE: THE COMPLETE DRUG REFERENCE, at v-viii (preface), 339–43 (entry for carbamazepine), 1378 (entry for formamide) (32nd ed. 1999)	Martindale 1999
1076	Groce & Kimbrough, *Acute and Subacute Toxicity in Sherman Strain Rats Exposed to 4,4'- And 2,2'-Dipyridyl*, 10 J. Toxicology & Environ. Health 363–72 (1982)	Groce
1077	Luu et al., *High-throughput 96-well solvent mediated sonic blending synthesis and on-plate solid/solution stability characterization of pharmaceutical cocrystals*, 441 Int'l J. Pharmaceutics 356–64 (2013)	Luu

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1078	Clarke et al., *Structure—Stability Relationships in Cocrystal Hydrates: Does the Promiscuity of Water Make Crystalline Hydrates the Nemesis of Crystal Engineering?*, 10 Crys. Growth & Des. 2152–67 (2010)	Clarke
1079	[Intentionally Blank]	
1080	Braga et al., *Innovation in crystal engineering*, 4 Cryst. Eng. Comm. 500–509 (2002)	Braga
1081	Sharma et al., *Molecular Recognition Involving an Interplay of O-H • • • O, C-H • • • O and π • • • π Interactions. The Anomalous Crystal Structure of the 1:1 Complex 3,5-Dinitrobenzoic Acid-4-(*N,N-*Dimethylamino)benzoic Acid*, 2 J. Chem. Soc. Perkin Trans. 2209–16 (1993)	Sharma
1082	Vishweshwar et al., *Molecular Complexes of Homologous Alkanedicarboxylic Acids with Isonicotinamide: X-ray Crystal Structures, Hydrogen Bond Synthons, and Melting Point Alternation*, 3 Crys. Growth & Des. 783–90 (2003)	Vishweshwar
1083	Zhu et al., *Artificial Intelligence Assisted Pharmaceutical Crystallization*, 24 Crys. Growth & Des. 4245−70 (2024)	Zhu