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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 IPR2023-01347
U.S. Patent No. 10,633,344

PETITIONER'S UPDATED EXHIBIT LIST

Exhibit	Description	Abbreviation
1501	U.S. Patent No. 10,633,344	'344 patent
1502	Declaration of Robin D. Rogers, Ph.D.	Rogers
1503	Declaration of Leah Appel, Ph.D.	Appel
1504	Hickey et al., <i>Performance comparison of a co-crystal of carbamazepine with marketed product</i> , 67 Eur. J. Pharm. & Biopharm. 112–19 (2007)	Hickey
1505	U.S. Patent No. 7,927,613	Almarsson
1506	MARTINDALE: THE COMPLETE DRUG REFERENCE, at v-x (preface), 1421–25 (entry for furosemide), 2117–19 (entry for nicotinamide) (37 th ed. 2011)	Martindale 2011
1507	Ueto et al., <i>Polymorphs and a Hydrate of Furosemide–Nicotinamide 1:1 Cocrystal</i> , 12 Crys. Growth & Des. 485–94 (2012)	Ueto
1508	Li et al., <i>New polymorphs of isonicotinamide and nicotinamide</i> , 47 Chem. Commun. 1530–32 (2011)	Li
1509	U.S. Pat. Pub. 2003/0224006 (published '956 priority application)	'006 Publication
1510	REMINGTON: ESSENTIALS OF PHARMACEUTICS at vii (Preface), 177–206 (Chapter 11: Molecular Structure, Properties, and States of Matter), 581–610 (Chapter 30: Oral Solid Dosage Forms) (2012 22 nd ed.)	Remington 2012
1511	P.401408 Specification, Claims, Drawings & State of the Art Report (with translation), “Documents from the filing date,” available at https://ewyszukiwarka.pue.uprp.gov.pl/search/pwp-details/P.401408?lng=en (accessed May 4, 2023)	'408 Application
1512	Sowa et al., <i>Cocrystals of fisetin, luteolin and genistein with pyridinecarboxamide coformers: crystal structures, analysis of intermolecular interactions, spectral and thermal characterization</i> , 15 CrysEngComm 7696–708 (2013)	Sowa

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1513	Marini et al., <i>Effects of the Phytoestrogen Genistein on Bone Metabolism in Osteopenic Postmenopausal Women</i> , 146 Ann. Internal Med. 839–47 (2007)	Marini
1514	U.S. Application No. 60/360,768	'768 application
1515	U.S. Application No. 10/378,956	'956 application
1516	Prosecution History of U.S. Patent 10,633,344 (foreign references removed)	'344 patent prosecution history
1517	Prosecution History of U.S. Patent Application No. 10/378,956 (foreign references removed)	'956 application prosecution history
1518	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
1519	Plaintiffs' Opening Claim Construction Brief (dated August 1, 2023); 3:22-cv-04913-AMO, D.I. 77	Plaintiffs' Claim Construction Brief
1520	Transcript of July 11, 2023 Deposition of Scott L. Childs, Ph.D., with errata, at 18, 27	Childs Dep. Tr.
1521	U.S. Patent Application No. 15/639,223	'223 application
1522	Prosecution History of U.S. Patent Application No. 15/639,223 (foreign references removed)	'223 prosecution history
1523	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
1524	Desiraju, <i>Chemistry beyond the molecule</i> , 412 Nature 397–400 (2001)	Desiraju 2001
1525	Aakeröy et al., <i>Do Polymorphic Compounds Make Good Cocrystallizing Agents? A Structural Case Study that Demonstrates the Importance of Synthron Flexibility</i> , 3 Crys. Growth & Des. 159–165 (2003)	Aakeröy 2003
1526	Dunitz, <i>Are crystal structures predictable?</i> , 5 Chem. Commun. 545–48 (2003)	Dunitz

Exhibit	Description	Abbreviation
1527	Reddy et al., <i>Phenyl-Perfluorophenyl Synthron Mediated Cocrystallization of Carboxylic Acids and Amides</i> , 4 Crys. Growth & Des. 89–94 (2004)	Reddy
1528	Fleischman et al., <i>Crystal Engineering of the Composition of Pharmaceutical Phases: Multiple-Component Crystalline Solids Involving Carbamazepine</i> , 3 Crys. Growth & Des. 909–19 (2003)	Fleischman
1529	Aitapamula et al., <i>Polymorphs and Solvates of a Cocrystal Involving an Analgesic Drug, Ethenzamide, and 3,5-Dinitrobenzoic Acid</i> , 10 Crys. Growth & Des. 2229–38 (2010)	Aitapamula
1530	Guillory, Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids, <i>in</i> POLYMORPHISM IN PHARMACEUTICAL SOLIDS, at 183–226 (1999)	Guillory
1531	21 C.F.R. § 184 (2000)	21 C.F.R. § 184 (2000)
1532	Moss et al., <i>Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure (IUPAC Recommendations 1995)</i> , 67 Pure & Appl. Chem. 1307–75, at 1307–10, 1316, 1341 (1995)	Moss
1533	Leigh et al., PRINCIPLES OF CHEMICAL NOMENCLATURE: A GUIDE TO IUPAC RECOMMENDATIONS, 14, 85 (1998)	IUPAC 1998
1534	Gavezzotti, <i>Are Crystal Structures Predictable?</i> , 27 Acc. Chem. Res. 309–14 (1994)	Gavezzotti
1535	PHYSICIANS' DESK REFERENCE, at 1048–52 (entry for Coumadin®), 1427–31 (entry for Amoxil®), 2665–68 (entry for Vibramycin® Hyclate) (58 th ed. 2004)	PDR 2004
1536	Hilton & Deasy, <i>Use of Hydroxypropyl Methylcellulose Acetate Succinate in an Enteric Polymer Matrix To Design Controlled-Release Tablets of Amoxicillin Trihydrate</i> , 82 J. Pharm. Scis. 737–43 (1993)	Hilton
1537	Coumadin® Label (Revised October 2011)	Coumadin® Label
1538	Vibramycin® Label (Revised December 2022)	Vibramycin® Label

Exhibit	Description	Abbreviation
1539	Amoxil [®] Label (Revised September 2015)	Amoxil [®] Label
1540	MARTINDALE: THE COMPLETE DRUG REFERENCE, at vii-viii (preface) (32 nd ed. 1999)	Martindale 1999
1541	REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, at xiii-xiv (preface), 1615-49 (Chapter 92: Oral Solid Dosage Forms) (19 th ed. 1995)	Remington 1995
1542	MERRIAM WEBSTER'S MEDICAL DICTIONARY, at 98 (1995)	Webster's Medical Dictionary
1543	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) (6 th ed. 2009)	Handbook of Pharmaceutical Excipients
1544	U.S. Patent No. 2,777,859	'859 patent
1545	U.S. Patent No. 7,807,196	'196 patent
1546	Jung et al., <i>Bioavailability of indomethacin-saccharin cocrystals</i> , 62 J. Pharm. & Pharmacol. 1560-68 (2010)	Jung
1547	U.S. Patent No. 7,183,272	Aronhime
1548	Aakeröy, <i>Crystal Engineering: Strategies and Architectures</i> , B53 Acta Cryst. 569-86 (1997)	Aakeröy 1997
1549	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	2001 Merck Index

Exhibit	Description	Abbreviation
	(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) (13 th ed. 2001)	
1550	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
1551	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
1552	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
1553	Curriculum Vitae of Robin D. Rogers, Ph.D.	Rogers CV
1554	Curriculum Vitae of Leah Appel, Ph.D.	Appel CV
1555	U.S. Patent No. 2,665,277	Homeyer
1556	U.S. Patent No. 3,664,858	Huffman

Exhibit	Description	Abbreviation
1557	U.S. Patent No. 5,023,092	DuRoss
1558	U.S. Patent No. 5,994,365	'365 patent
1559	U.S. Patent No. 6,559,293	'293 patent
1560	CA 1148020A1	McCoy
1561	GB 2169601	Jackson
1562	JP-B-46-33588 (UM00014569-71)	Sanzu
1563	Ammar & Omar, <i>Effect of Aromatic Hydrotropes on the Solubility of Carbamazepine. Part II: Effect of Nicotinamide, Sodium Salts of Benzoic, Naphthoic and Nicotinic Acids</i> , 35 Egypt J. Pharmaceut. Sci. 209–23 (1994)	Ammar
1564	Caira, <i>Molecular complexes of sulfonamides. 3. Structure of 5-methoxysulfadiazine (Form II) and its 1:1 complex with acetylsalicylic acid</i> , 24 J. Chem. Crystallogr. 695–701 (1994)	Caira
1565	Desiraju, <i>Supramolecular Synthons in Crystal Engineering—A New Organic Synthesis</i> , 34 Angew. Chem. Int'l Ed. Engl. 2311–27 (1995)	Desiraju 1995
1566	Freemont et al., <i>Cocrystal structure of an editing complex of Klenow fragment with DNA</i> , 85 Proc. Nat'l Acad. Sci. 8924–28 (1998)	Freemont
1567	Smith et al., <i>The utility of 4-aminobenzoic acid in promotion of hydrogen bonding in crystallization processes: the structures of the cocrystals with halo and nitro substituted 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)</i> , 27 J. Chem. Crystallogr. 307–17 (1997)	Smith
1568	[Intentionally Blank]	
1569	[Intentionally Blank]	
1570	[Intentionally Blank]	

Exhibit	Description	Abbreviation
1571	[Intentionally Blank]	
1572	Housecroft & Sharpe, INORGANIC CHEMISTRY, at 270 (4 th ed. 2012)	Housecroft 2012
1573	Huheey et al., INORGANIC CHEMISTRY: PRINCIPLES OF STRUCTURE AND REACTIVITY, at 370 (4 th ed. 1993)	Huheey 1993
1574	Das & Baruah, <i>Supramolecular Synthons and Hydrates in Stabilization of Multicomponent Crystals of Nicotinamide and Isonicotinamide with N-Containing Aromatic Dicarboxylic Acids</i> , 11 Crys. Growth & Des. 5522–32 (2011)	Das
1575	Vippagunta et al., <i>Crystalline Solids</i> , 48 Adv. Drug Deliv. Revs. 3–26 (2001)	Vippagunta
1576	Palleros, Basic Concepts, in EXPERIMENTAL ORGANIC CHEMISTRY 19–44 (2000)	Palleros
1577	Olmsted & Williams, Effect of Intermolecular Forces, in CHEMISTRY, THE MOLECULAR SCIENCES 449–511 (2 nd ed. 1997)	Olmsted
1578	Ansel et al., Capsules and Tablets, in PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 179–228 (7 th ed. 1999)	Ansel
1579	THE MERCK INDEX, at v–xiv (foreword, acknowledgments, explanatory notes), 740 (entry 4309, furosemide), 756–57 (entry 4391, genistein) (14 th ed. 2006)	2006 Merck Index
1580	PHYSICIANS’ DESK REFERENCE, at 2411–13 (entry for furosemide) (65 th ed. 2011)	PDR 2011
1581	“Furosemide,” PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/Furosemide (accessed August 20, 2023)	PubChem Entry Furosemide
1582	“Nicotinamide,” PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/Nicotinamide (accessed August 20, 2023)	PubChem Entry Nicotinamide

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1583	“Genistein,” PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/Genistein (accessed August 20, 2023)	PubChem Entry Genistein
1584	“Water,” PubChem, National Institutes of Health – National Library of Medicine, available at https://pubchem.ncbi.nlm.nih.gov/compound/Water (accessed August 20, 2023)	PubChem Entry Water
1585	EUROPEAN COMMISSION, <i>Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin)</i> , SCF/CS/NUT/UPPLEV/39 (2002)	European Commission Opinion on Tolerable Upper Intake Levels of Nicotinamide
1586	P.401408 Patent Application Details (with translation), available at https://ewyszukiwarka.pue.uprp.gov.pl/search/pwp-details/P.401408?lng=en (accessed May 4, 2023)	P.401408 Patent Application Details
1587	Derwent Search Report for P.401408, available at https://www.derwentinnovation.com/ui/en/#/home/record-view?guid=PL401408A120130610 (accessed August 17, 2023 via https://www.derwentinnovation.com/login/ using login credentials, then via https://www.derwentinnovation.com/ui/en/#/home using search term “PL401408A1”)	Derwent Search Report for P.401408
1588	Espacenet Results List for PL401408, available at https://worldwide.espacenet.com/patent/search/family/048539640/publication/PL401408A1?q=PL401408 (accessed August 17, 2023)	Espacenet Results List for PL401408
1589	Declaration of Christina Schwarz Regarding Exhibits 1511, 1586, 1587, 1588	Attorney Declaration of C. Schwarz
1590	July 24, 2024 E-mail from Michael Kane to Erin Belfield, et al., regarding Petitioner’s Request for Authorization to File Motion for Adverse Judgment	Kane E-mail, July 24, 2024

Exhibit	Description	Abbreviation
1591	July 31, 2024 E-mail from the Board to Erin Belfield, et al., regarding Petitioner's Request for Authorization to File Motion for Adverse Judgment	Board E-mail, July 31, 2024
1592	Transmittal Letter, Statutory Disclaimer, and Payment Receipt filed June 6, 2024 in File History of U.S. Patent No. 10,633,344, accessed via Patent Center	Transmittal Letter, Statutory Disclaimer, and Payment Receipt filed June 6, 2024, accessed via Patent Center