

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
WOCKHARDT BIO AG, TEVA PHARMACEUTICALS USA, INC.,  
AUROBINDO PHARMA U.S.A. INC., and SUN PHARMACEUTICAL  
INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE  
and AMNEAL PHARMACEUTICALS LLC,  
Petitioners,

v.

ASTRAZENECA AB,  
Patent Owner.

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Case IPR2015-01340  
Patent RE44,186 E<sup>1</sup>

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**PETITIONERS' EXHIBIT LIST AND  
NOTICE SUBMITTING EXHIBITS 1060B & 1062B**  
37 CFR §§42.6(c) & 42.63(e)

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<sup>1</sup> Wockhardt from IPR2016-01029, Teva from IPR2016-01122, Aurobindo from IPR2016-01117, and Sun/Amneal from IPR2016-01104 has each been joined as a Petitioner to this proceeding.

On 10 January 2017, AstraZeneca electronically requested authorization for the parties to submit less-redacted versions of specified exhibits, including exhibits 1060A and 1062A. On the same day, the Board granted the request, specifying that these exhibits be submitted as exhibits 1060B and 1062B, respectively.

Mylan (on behalf of Petitioners) submits less-redacted exhibits 1060B and 1062B, along with the following updated exhibit list.

<b>Exhibit No.</b>	<b>Description</b>
1001	U.S. Reissue Patent 44,186 E to Robl et al. (reissued Apr. 30, 2013)
1002	U.S. Patent No. 6,395,767 to Robl et al. (issued May 28, 2002)
1003	Declaration of David P. Rotella, Ph.D.
1004	<i>Curriculum Vitae</i> of David P. Rotella, Ph.D.
1005	File History of U.S. Patent No. 6,395,767 to Robl et al.
1006	File History of U.S. Reissued Patent 44,186 E to Robl et al.
1007	Doreen M. Ashworth et al., <i>2-cyanopyrrolidides as potent, stable inhibitors of dipeptidyl peptidase IV</i> , 6 BIOORG. & MED. CHEM. LTRS. 1163 (1996)
1008	WO Patent App. Pub. No. 98/19998 to Villhauer (pub'd May 14, 1998)
1009	Reetta Raag & Thomas L. Poulos, <i>Crystal Structure of Cytochrome P-450<sub>CAM</sub> Complexed with Camphane, Thiocamphor, and Adamantane: Factors Controlling P-450 Substrate Hydroxylation</i> , 30 BIOCHEMISTRY 2674 (1991)
1010	Stephen Hanessian et al., <i>The Synthesis of Enantiopure ω-Methanoprolines and ω-Methanopiperic Acids by a Novel Cyclopropanation Reaction: The "Flattening" of Proline</i> , 36 ANGEW. CHEM. ED. ENGL. 1881 (1997)
1011	WO Patent App. Pub. No. 99/38501 to Bachovchin et al. (pub'd Aug. 5, 1999)
1012	GLUCOPHAGE Label (available by FOIA Jan. 8, 1998)
1013	XENICAL Label (available by FOIA Aug. 9, 1999)
1014	MEVACOR Label (available by FOIA Sept. 15, 1994)

Exhibit No.	Description
1015	Jian Lin et al., <i>Inhibition of dipeptidyl peptidase IV by fluoroolefin-containing N-peptidyl-O-hydroxylamine peptidomimetics</i> , 95 PROC. NATL. ACAD. SCI. USA 14020 (1998)
1016	Howard E. Hoffman et al., <i>Pharmacokinetics and Metabolism of Rimantadine Hydrochloride in Mice and Dogs</i> , 32(11) ANTIMICROBIAL AGENTS AND CHEMOTHERAPY 1699 (1988)
1017	Christopher A. Lipinski et al., <i>Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings</i> , 23 ADV. DRUG DELIV. REV. 3 (1996)
1018	Hansch et al., <i>Cluster Analysis and the Design of Congener Sets</i> , in SUBSTITUENT CONSTANTS FOR CORRELATION ANALYSIS IN CHEMISTRY AND BIOLOGY 48 (John Wiley & Sons 1979)
1019	Lindley A. Cates, <i>Calculation of Drug Solubilities by Pharmacy Students</i> , 45 AM. J. PHARM. EDUC. 11 (1981)
1020	Walter A. Korfmacher et al., <i>HPLC-API/MS/MS: a powerful tool for integrating drug metabolism into the drug discovery process</i> , 2 DRUG DISC. TODAY 532 (1997)
1021	C. Y. Chiou et al., <i>The Cholinergic Effects and Rates of Hydrolysis of Conformationally Rigid Analogs of Acetylcholine</i> , 166 J. PHARM. EXP. THER. 243 (1969)
1022	Daniel E. Koshland, Jr., <i>The Key-Lock Theory and the Induced Fit Theory</i> , 33 ANGEW. CHEM. ED. ENGL. 2375 (1994)
1023	E.J. Ariëns & A. M. Simonis, <i>Optimization of Pharmacokinetics – An Essential Aspect of Drug Development – by Metabolic Stabilization</i> , <i>Pharmacochem. Lib.</i> , in 4 PHARMACOCHEM. LIB. 165 (1982)
1024	R. Scott Obach, <i>Prediction of Human Clearance of Twenty-nine Drugs from Hepatic Microsomal Intrinsic Clearance Data: An Examination of In Vitro Half-life Approach and Nonspecific Binding to Microsomes</i> , 27 DRUG METAB. DISPOS. 1350 (1999)
1025	Yung-chi Cheng & William H. Prusoff, <i>Relationship Between the Inhibition Constant (<math>K_I</math>) and the Concentration of Inhibitor which Causes 50 Per Cent Inhibition (<math>I_{50}</math>) of an Enzymatic Reaction</i> , 22 BIOCHEM. PHARMACOL. 3099 (1973)

Exhibit No.	Description
1026	Debnath Pal & Pinak Chakrabarti, <i>Cis Peptide Bonds in Proteins: Residues Involved, their Conformations, Interactions and Location</i> , 294 J. OF MOL. BIOL. 271 (1999)
1027	US Provisional Patent Application No. 60/1888,555 to Robl
1028	Cross-Examination of Dr. James Lenhard, Excerpts from Transcript of Day 2 of Bench Trial in 14-664-GMS, 14-666-GMS, and 14-667-GMS (September 20, 2016)
1029	Cross-Examination of Dr. Christine Meyer, Excerpts from Transcript of Day 3 of Bench Trial in 14-664-GMS, 14-666-GMS, and 14-667-GMS (September 20, 2016)
1030	What is JANUVIA® (sitagliptin) tablets?, obtained from <a href="http://www.januvia.com/sitagliptin/what-is-januvia/">http://www.januvia.com/sitagliptin/what-is-januvia/</a> (September 20, 2016)
1031	Why Tradjenta® (linagliptin) Tablets?, obtained from <a href="https://www.tadjenta.com/about">https://www.tadjenta.com/about</a> (September 20, 2016)
1032	(JTX-146) FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin (2016).
1033	(JTX-196) ONGLYZA Label (2016).
1034	Demonstrative Exhibits Referenced During Cross-Examination of Christine S. Meyer, Ph.D. in 14-664-GMS, 14-666-GMS, and 14-667-GMS (2016)
1035	(PTX-2344) Reply Expert Report of Ivan T. Hofmann, CPA/CFF, CLP in 14-cv-00664-GMS (Consolidated) (PROTECTIVE ORDER MATERIAL).
1036	ADVAIR Label (2008)
1037	CYMBALTA Label (2010)
1038	Mushtaq et al., <i>A Study of the Current Prescribing Patterns of Dipeptidyl Peptidase 4 Inhibitors in a Multi Speciality Hospital Outpatient Setting</i> , 7 ASIAN J. PHARM. CLIN. RES. 134 (2014)
1039	Long-term Trends in Diabetes, CDC's Division of Diabetes Translation (April 2016)
1040	Kabadi, <i>Sulfonylurea Glimepiride: A Proven Cost Effective, Safe and Reliable War Horse in Combating Hyperglycemia in Type 2 Diabetes</i> , 5 JOURNAL OF DIABETES MELLITUS 211 (2015)
1041	Declaration of Robert J. Tanenberg, M.D., FACP

<b>Exhibit No.</b>	<b>Description</b>
1042	<i>Curriculum Vitae</i> of Robert J. Tanenberg, M.D., FACP
1043	World Health Organization List of Essential Medicines for the Treatment of Diabetes, 19 <sup>th</sup> Edition
1044	2008 Novartis Annual Report
1045	2009 Novartis Annual Report
1046	2010 Novartis Annual Report
1047	2011 Novartis Annual Report
1048	2012 Novartis Annual Report
1049	2013 Novartis Annual Report
1050	2014 Novartis Annual Report
1051	2015 Novartis Annual Report
1052	2008 Merck Annual Report
1053	2009 Merck Annual Report
1054	2010 Merck Annual Report
1055	2011 Merck Annual Report
1056	2012 Merck Annual Report
1057	2013 Merck Annual Report
1058	2014 Merck Annual Report
1059	2015 Merck Annual Report
1060	Redacted Declaration of DeForest McDuff, Ph.D.
1060A	Declaration of DeForest McDuff, Ph.D. (PROTECTIVE ORDER MATERIAL).
1060B	Declaration of DeForest McDuff, Ph.D. (PROTECTIVE ORDER MATERIAL).
1061	McDuff Attachment A (McDuff CV)
1062	Redacted McDuff Attachments B-1a through B-10b
1062A	McDuff Attachments B-1a through B-10b (PROTECTIVE ORDER MATERIAL).
1062B	McDuff Attachments B-1a through B-10b (PROTECTIVE ORDER MATERIAL).
1063	Mestre-Ferrandiz, Jorge, Jon Sussex, and Adrian Towse , <i>The R&amp;D Cost of a New Medicine</i> , OFFICE OF HEALTH ECONOMICS, London UK, 1–86 (2012)
1064	DiMasi, Joseph, Henry Grabowski, and Ronald Hansen , <i>Innovation in the pharmaceutical industry: New estimates of R&amp;D costs</i> , JOURNAL OF HEALTH ECONOMICS 47: 20–33 (2016)

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