

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,

Patent Owner

IPR2016-01563

U.S. Patent No. 8,673,927

PATENT OWNER'S PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107

TABLE OF CONTENTS

I. INTRODUCTION iv

II. TECHNICAL OVERVIEW OF THE INVENTION9

**III. MYLAN FALLS SHORT OF ESTABLISHING THAT CLAIMS
18-24 OF THE ‘927 PATENT ARE ANTICIPATED.....14**

**IV. MYLAN FALLS FAR SHORT OF ESTABLISHING THAT THE
GLUCOPHAGE LABEL IS A PRINTED PUBLICATION.....19**

A. A Reference Must Have Been “Publicly Accessible” To be A
Printed Publication20

B. The Glucophage Label (Exhibit 1004) Is Not A Section 102(b)
Printed Publication Because There Is No Evidence That It Was
Publicly Accessible21

**V. MYLAN FAILS TO ESTABLISH A REASON TO COMBINE
THE TEACHING OF PRIOR ART REFERENCES OR
REASONABLE EXPECTATION OF SUCCESS.....24**

A. A Person of Skill in the Art Would Have Had No Reason To
Select Linagliptin Of All Available DPP-IV Inhibitors.....25

B. A Person of Skill in the Art Would Have Had No Reason To
Select Metformin as a Combination Partner for Linagliptin.....28

C. A Person of Skill In The Art Would Have Had No Reason To
Modify the Teachings of the Cited Art to Arrive at the Claimed
Linagliptin Dosages.....34

D. A Person of Skill In The Art Would Have Had No Reason To
Modify the Teachings of the Cited Art to Arrive at the Claimed
Metformin Dosages39

VI. CONCLUSION40

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Apple Inc. v. DSS Tech. Mgmt., Inc.</i> , Case IPR2015-00369, Paper 14 (P.T.A.B. Aug. 12, 2015).....	24
<i>Atofina v. Great Lakes Chem. Corp.</i> , 441 F.3d 991 (Fed. Cir. 2006)	17
<i>Coal. for Affordable Drugs IV LLC v. Pharmacyclics, Inc.</i> , IPR2015-01076, 2015 WL 7303857 (P.T.A.B. Oct. 19, 2015).....	23
<i>In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.</i> , 676 F.3d 1063 (Fed. Cir. 2012)	24
<i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.</i> , IPR2014-01162, 2015 WL 5578357 (P.T.A.B. Jan. 29, 2015)	18
<i>E Ink Corp. v. Research Frontiers Inc.</i> , IPR2014-00422, 2014 WL 4078636 (P.T.A.B. Aug. 14, 2014).....	19
<i>Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH</i> , Case IPR2016-00649, Paper 10 (P.T.A.B. September 1, 2016).....	21, 22, 23, 24
<i>Janssen Pharm., Inc. v. Watson Labs., Inc.</i> , Case No. 08-5103, 2012 WL 3990221 (D.N.J. 2012).....	35
<i>Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.</i> , 730 F.2d 1452 (Fed. Cir. 1984)	17
<i>Net MoneyIN, Inc. v. VeriSign, Inc.</i> , 545 F.3d 1359, 1371 (Fed. Cir. 2008)	16
<i>Northern Telecom, Inc. v. Datapoint Corp.</i> , 908 F.2d 931 (Fed. Cir. 1990)	20
<i>OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.</i> , 701 F.3d 698 (Fed. Cir. 2012)	17

<i>Sanofi–Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075 (Fed. Cir. 2008)	17
<i>SRI Int’l, Inc. v. Internet Sec. Sys., Inc.</i> , 511 F.3d 1186 (Fed. Cir. 2008)	20
<i>Therasense, Inc. v. Becton, Dickinson & Co.</i> , 593 F.3d 1325 (Fed. Cir. 2010)	17
<i>Volkswagen Grp. of Am., Inc. v. Emerachem Holdings, LLC</i> , IPR2014-01555, 2015 WL 1250947 (P.T.A.B. Mar. 16, 2015).....	19
Statutes	
35 U.S.C. § 102	8, 24
35 U.S.C. §102(b)	14, 20, 21
35 U.S.C. §311(b)	20, 24
Other Authorities	
MANUAL OF PATENT EXAMINING PROCEDURE § 2131.03 (2015)	18

INDEX OF EXHIBITS

Exhibit No.	Description
2001	<i>A Snapshot: Diabetes in the United States</i> , Centers for Disease Control and Prevention (2014)
2002	Nathan, D.M., et al., <i>Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy, A Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes</i> , <i>Diabetes Care</i> , 29(8): 1963-1972, (2006)
2003	<i>Screening for Type 2 Diabetes – Report of a World Health Organization and International Diabetes Federation Meeting</i> , World Health Organization, Geneva, Switzerland (2003)
2004	Szablewski, L., <i>Glucose Homeostasis – Mechanism and Defects</i> , <i>Diabetes - Damages and Treatments</i> , Prof. Everlon Rigobelo (Ed.), ISBN: 978-953-307-652-2, In Tech, 227-256 (2011). Available at: http://www.intechopen.com/books/diabetes-damages-and-treatments/glucose-homeostasis-mechanism-and-defects
2005	Boron, W.E. and Boulpaep, E.L., <i>Medical Physiology – A Cellular and Molecular Approach</i> , Elsevier Science: Pennsylvania, 1066-1085 (2003)
2006	Aronoff, S.L., et al., <i>Glucose Metabolism and Regulation: Beyond Insulin and Glucagon</i> , <i>Diabetes Spectrum</i> , 17(3):183-190 (2004)
2007	Green, B.D., et al., <i>Inhibition of Dipeptidyl Peptidase IV Activity as a Therapy of Type 2 Diabetes</i> , <i>Expert Opin. Emerging Drugs</i> , 11(3):525-539 (2006)
2008	Nathan, D.M., et al., <i>Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy, A Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes</i> , <i>Diabetes Care</i> , 32(1):193-203 (2009)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.