UNITED STA	TES PATENT AND TRADEMARK OFFICE
BEFORE TH	IE PATENT TRIAL AND APPEAL BOARD
MY	LAN PHARMACEUTICALS INC., Petitioner
BOEHRINGE	v. ER INGELHEIM INTERNATIONAL GMBH,
	Patent Owner
	IPR2016-01565 U.S. Patent No. 8,853,156

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



TABLE OF CONTENTS

I.	INT	RODUCTION	1
II.	TEC	CHNICAL OVERVIEW OF THE INVENTION	3
III.		OUNDS 1 AND 2: MIKHAIL IS NOT PRIOR ART TO THE PATENT	9
IV.	MYLAN FALLS FAR SHORT OF ESTABLISHING THAT THE JANUVIA LABEL AND HUETTNER ARE PRINTED PUBLICATIONS		
	A.	A Reference Must Have Been "Publicly Accessible" To be A Printed Publication	11
	B.	The Januvia Label (Exhibit 1006) Is Not A Section 102(b) Printed Publication Because There Is No Evidence That It Was Publicly Accessible	12
	C.	Huettner (Exhibit 1004) Is Not A Section 102(b) Printed Publication Because There Is No Evidence That It Was Publicly Accessible	17
	D.	Mylan Has Not Presented Any Competent Expert Testimony Indicating that the Januvia Label and Huettner Are "Printed Publications"	19
V.	THE	LAN FAILS TO ESTABLISH A REASON TO COMBINE E TEACHING OF PRIOR ART REFERENCES OR ASONABLE EXPECTATION OF SUCCESS	20
	A.	A Person of Skill in the Art Would Have Had No Reason To Select Linagliptin Of All Available DPP-IV Inhibitors	21
		1. Renal Impairment Affects Hepatic Drug Metabolism	21
		2. Huettner Would Not Have Led a Person of Skill in the Art to Linagliptin	25
		3. The Knowledge of a Person of Skill in the Art Would Not Have Led a Person of Skill in the Art to Linagliptin	26



		4. A Skilled Artisan Would Not Have Looked to Other DPP-IV Inhibitors To Determine the Suitable Uses For Linagliptin	27
	В.	A Person of Skill in the Art Would Have Had No Reason To Administer DPP-IV Inhibitors to Patients For Whom Metformin Therapy Is Inappropriate Due to at Least One	
		Contraindication	30
VI.	CON	ICLUSION	31



TABLE OF AUTHORITIES

Page(s)
Cases
Apple Inc. v. DSS Tech. Mgmt., Inc., IPR2015-00369, Paper No. 14 (P.T.A.B. Aug. 12, 2015)
Cisco Sys. v. Constellation Techs., IPR2014-01085, Paper 11 (P.T.A.B. Jan. 9, 2015)
Coal. for Affordable Drugs IV LLC v. Pharmacyclics, Inc., No. IPR2015-01076, 2015 WL 7303857 (P.T.A.B. Oct. 19, 2015)
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012)
Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH, Case IPR2016-00649, Paper 10 (P.T.A.B. September 1, 2016)13, 14, 19, 20
<i>In Re Klopfenstein</i> , 380 F.3d 1345 (Fed. Cir. 2004)
Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931 (Fed. Cir. 1990)
SRI Int'l, Inc. v. Internet Sec. Sys., Inc., 511 F.3d 1186 (Fed. Cir. 2008)
Statutes
35 U.S.C. § 102
35 U.S.C. § 102(b)
35 U.S.C. §311(b)



INDEX OF EXHIBITS

Exhibit No.	Description
2001	A Snapshot: Diabetes in the United States, Centers for Disease Control and Prevention, (2014)
2002	American Diabetes Association, Standards of Medical Care in Diabetes—2016, Diabetes Care, 39(S1):S1-S98 (2016)
2003	Screening for Type 2 Diabetes – Report of a World Health Organization and International Diabetes Federation Meeting, World Health Organization, Geneva, Switzerland (2003)
2004	Szablewski, L., <i>Glucose Homeostasis – Mechanism and Defects</i> , Diabetes - Damages and Treatments, 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> , Diabetes Spectrum, 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> , Expert Opin. Emerging Drugs, 11(3):525-539 (2006)
2008	Nathan, D.M., et al., 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, Diabetes Care, 29(8):1963-1972 (2006)



DOCKET

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.

