

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICRO LABS LIMITED AND MICRO LABS USA INC.,
Petitioner,

v.

SANTEN PHARMACEUTICAL CO., LTD. AND
ASAHI GLASS CO., LTD.,
Patent Owner.

Case IPR2017-01434
U.S. Patent No. 5,886,035

PATENT OWNER PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	6
	A. State of the Art as of the Priority Date of the '035 Patent, December 26, 1996	6
	B. The '035 Patent	15
	C. Prosecution History of the '035 Patent	23
III.	LEVEL OF ORDINARY SKILL IN THE ART	25
IV.	CLAIM CONSTRUCTION	26
V.	CLAIMS 1-14 OF THE '035 PATENT WOULD NOT HAVE BEEN OBVIOUS AS OF DECEMBER 26, 1996	27
	A. Legal Standard Regarding Obviousness Based on Identification of an Alleged Lead Compound.....	30
	B. A POSITA Would Not Have Considered Compound C of Klimko To Be a Suitable Lead Compound	32
	C. It Would Not Have Been Obvious to Modify Compound C of Klimko by C15 Fluorination	45
	D. It Would Not Have Been Obvious to Difluorinate Compound C of Klimko	49
	E. Klimko Specifically Excluded C15 Difluorinated Compounds from the Scope of Its Work.....	55
VI.	CONCLUSION.....	59
	CLAIM LISTING APPENDIX	60
	CERTIFICATE OF COMPLIANCE.....	63
	CERTIFICATE OF SERVICE	64

TABLE OF AUTHORITIES

Cases

<i>Otsuka Pharm. Co. v. Sandoz, Inc.</i> , 678 F.3d 1280 (Fed. Cir. 2012)	32, 33
<i>Pfizer Inc. v. Teva Pharm. USA, Inc.</i> , 555 F. App'x 961 (Fed. Cir. 2014)	30, 31
<i>Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.</i> , 492 F.3d 1350 (Fed. Cir. 2007)	31, 32, 33

LIST OF EXHIBITS

Exhibit No.	Document
2001	Declaration of Timothy L. Macdonald, Ph.D.
2002	Declaration of Robert D. Fechtner, M.D.
2003	Camras <i>et al.</i> , "Reduction of intraocular pressure by prostaglandins applied topically to the eyes of conscious rabbits," <i>Invest. Ophthalmol. Vis. Sci.</i> 16:1125-1134 (1977)
2004	"Pharmacia Cleared To Market Xalatan, Drug for Glaucoma," <i>Wall St. J.</i> B7 (June 7, 1996)
2005	Fung and Whitson, "An evidence-based review of unoprostone isopropyl ophthalmic solution 0.15% for glaucoma: place in therapy," <i>Clin. Ophthalmol.</i> 8:543-554 (2014)
2006	Linden and Alm, "Prostaglandin Analogues in the Treatment of Glaucoma," <i>Drug Aging</i> , 14(5):387-398 (1999)
2007	Coleman <i>et al.</i> , "VIII. International Union of Pharmacology Classification of Prostanoid Receptors: Properties, Distribution, and Structure of the Receptors and Their Subtypes," <i>Pharmacol. Rev.</i> 46(2):205-229 (1994)
2008	Konturek and Pawlik, "Physiology and pharmacology of prostaglandins," <i>Dig. Dis. Sci.</i> 31(2 Suppl):6S-19S (1986)
2009	Stjernschantz and Alm, "Latanoprost as a new horizon in the medical management of glaucoma," <i>Curr. Opin. Ophthalmol.</i> 7(2):11-17 (1996)
2010	Collins and Djuric, "Synthesis of Therapeutically Useful Prostaglandin and Prostacyclin Analogs," <i>Chem. Rev.</i> 93:1533-1564 (1993)
2011	Giuffrè, "The effects of prostaglandin F _{2α} in the human eye," <i>Graefe's Arch. Clin. Exp. Ophthalmol.</i> 222:139-141 (1985)
2012	Bito and Baroody, "The ocular pharmacokinetics of eicosanoids and their derivatives: 1. Comparison of ocular eicosanoid penetration and distribution following the topical application of PGF _{2α} , PGF _{2α} -1-methyl ester, and PGF _{2α} -1-isopropyl ester," <i>Exp. Eye Res.</i> 44:217-26 (1987)
2013	Villumsen and Alm, "Prostaglandin F _{2α} -isopropylester eye drops: effects in normal human eyes," <i>Br. J. Ophthalmol.</i> 73:419-26 (1989)
2014	Villumsen and Alm, "Ocular effects of two different prostaglandin F _{2α} esters: a doublemasked cross-over study on normotensive eyes," <i>Acta Ophthalmol.</i> 68:341-343 (1990)

Exhibit No.	Document
2015	Camras and Alm, "Initial Clinical Studies with Prostaglandins and Their Analogues," <i>Surv. Ophthalmol.</i> 41(Suppl. 2):S61-S68 (1997)
2016	Camras, "Prostaglandins," in <i>The Glaucomas</i> 69:1449-1461 (1996)
2017	European Patent Application No. 0364417 A1
2018	Qiu, "Revisit Rescula and Cystoid Macular Edema and Refractory Glaucoma," <i>J. Clin. Exp. Ophthalmol.</i> 6:5 (2015)
2019	"R-Tech Ueno Starts Early Phase II Clinical Trial For RK-023" (2009)
2020	Schoenwald and Ward, "Relationship between Steroid Permeability across Excised Rabbit Cornea and Octanol-Water Partition Coefficients," <i>J. Pharm. Sci.</i> 67(6):786-788 (1978)
2021	Klimko <i>et al.</i> , "15-Fluoro prostaglandin FP agonists: a new class of topical ocular hypotensives," <i>Bioorg. Med. Chem.</i> 12:3451-3469 (2004)
2022	WO 1995/026729

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.