Trials@uspto.gov
571-272-7822

Paper 11
Entered: November 29, 2017

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
Patent 5,886,035

Before LORA M. GREEN, JO-ANNE M. KOKOSKI, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

KOKOSKI, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Micro Labs Limited and Micro Labs USA Inc. (collectively, "Petitioner") filed a Petition ("Pet.") to institute an *inter partes* review of claims 1–14 of U.S. Patent No. 5,886,035 ("the '035 patent," Ex. 1001). Paper 1. Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (collectively, "Patent Owner") filed a Preliminary Response ("Prelim. Resp."). Paper 10.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon consideration of the Petition and Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to the unpatentability of claims 1–14 of the '035 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

The parties indicate that the '035 patent is being asserted in *Santen Pharmaceutical Co., Ltd. v. Micro Labs Limited*, Case No. 16-cv-00353 (D. Del. 2016) and *Santen Pharmaceutical Co., Ltd. v. Sandoz Inc.*, Case No. 16-cv-00354 (D. Del. 2016). Pet. 4; Paper 3, 1.

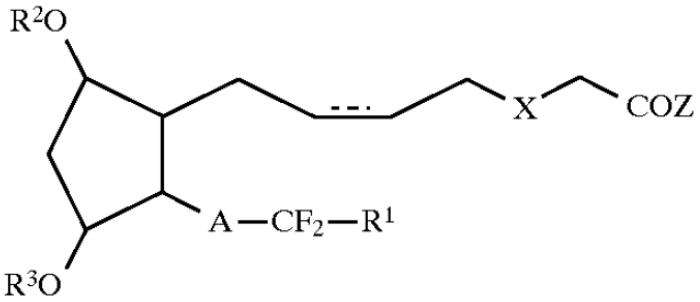
B. The '035 Patent

The '035 patent, titled "Difluoroprostaglandin Derivatives and Their Use," is directed to "fluorine-containing prostaglandin derivatives having two fluorine atoms at the 15-position (or their salts) and medicines containing the compounds as an active ingredient, particularly, preventative

or therapeutic medicines for eye diseases." Ex. 1001, 1:4–8. These compounds are derivatives of a class of prostaglandins referred to as "prostaglandin Fs" or "PGFs." *Id.* at 1:11–21, 61–63. The '035 patent states that, although naturally-occurring prostaglandin Fs "are known to lower intraocular pressure when topically applied to the eye," they are also "irritant to the eye and have a problem of their inflammatory side effects such as congestion and damage to the cornea" (*id.* at 1:12–19), and "extensive research has been conducted both at home and abroad for development of long-lasting PGF derivatives having much the same biological activities as the naturally occurring one and few side effects" (*id.* at 1:44–47).

In that regard, the '035 patent discloses that "15,15-difluoro-15-deoxy-$PGF_{2\alpha}$ and its derivatives are superior to the known natural $PGF_{2\alpha}$ in the effect of lowering intraocular pressure[,] are scarcely irritant to the eye, scarcely affect the ocular tissues such as the cornea, the iris, and the conjunctive, and have long-lasting efficacy." *Id.* at 2:7–12. The disclosed fluorine-containing prostaglandin derivatives also "are unlikely to decompose through metabolic processes such as hydrolysis and oxidation and [are] stable in the body," and "hardly stimulate melanogenesis." *Id.* at 19:21–28. As a result, "the medicine of the present invention is effective as a therapeutic agent, particularly for glaucoma or ocular hypertension." *Id.* at 29–31.

The fluorine-containing prostaglandin derivatives disclosed in the '035 patent have the following generic formula:

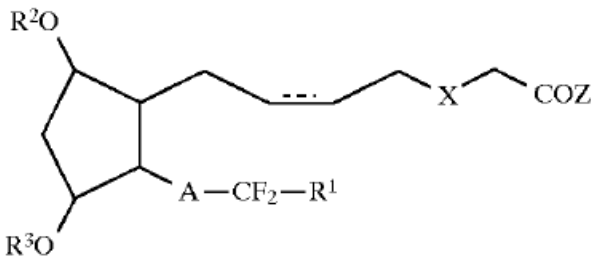


Ex. 1001, 2:20–29. These fluorine-containing derivatives "may be the same as the naturally occurring type except for the two fluorine atoms at the 15-position", i.e., "compounds wherein A is a vinylene group, R^1 is a n-pentyl group, both R^2 and R^3 are hydrogen atoms, X is $–CH_2–$, Z is –OH, and the dual line is a cis-double bond." *Id.* at 2:53–58. The '035 patent further teaches that fluorine-containing prostaglandin derivatives "having an ω-chain which is not of the naturally[-]occurring type (namely, wherein A is a vinylene group, and R^1 is a n-pentyl group) are preferred." *Id.* at 2:59–62; *see also id.* at 4:11–7:53 (setting forth compounds for A, X, R^1–R^7, and Z that "are preferred from the standpoint of biological activities and physical properties").

C. Challenged Claims

Petitioner challenges claims 1–14 of the '035 patent. Claims 1 and 12 are the only independent claims, and are reproduced below.

> 1. A fluorine-containing prostaglandin derivative of the following formula (1) or a salt thereof:



(1)

wherein A is an ethylene group, a vinylene group, an ethylene group, $–OCH_2–$ or $–SCH_2–$,

R^1 is a substituted or unsubstituted aryloxyalkyl group,

each of R^2 and R^3 which are independent of each other, is a hydrogen atom or an acyl group, or forms a single bond together with Z,

X is $–CH_2–$, –O– or –S–,

Z is $–OR^4$, $–NHCOR^5$, $–NHSO_2R^6$ or $–SR^7$, or forms a single bond together with R^2 or R^3,

each of R^4, R^5, R^6 and R^7 which are independent of one another, is a hydrogen atom, an alkyl group, an alkenyl group, an alkynyl group, a cycloalkyl group, an aryl group or an aralkyl group,

and a dual line consisting of solid and broken lines is a single bond, a cis-double bond or a trans-double bond.

Ex. 1001, 31:2–26

12. A medicine containing 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin $F_{2\alpha}$, 16-(3-chlorophenoxy)-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin $F_{2\alpha}$, 16-phenoxy-15-deoxy-15,15-difluoro-13,14-dihydro-17,18,19,20-tetranorprostaglandin $F_{2\alpha}$ or an alkyl ester or salt thereof as an active agent.

Id. at 32:22–27.

D. The Prior Art

Petitioner relies on the following prior art references:

Reference	Description	Date	Exhibit No.
Kishi	U.S. 5,292,754	Mar. 8, 1994	1005
Klimko	EP 0 639 563 A2	Feb. 22, 1995	1003
Ueno[1]	Japanese Unexamined Patent App. Pub. No. H7-70054	Mar. 14, 1995	1006

[1] Ueno is a Japanese patent application, and Petitioner provided an English-language translation as required by 37 C.F.R. § 42.63(b). Our citations are

DOCKET ALARM

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.