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Paper 53
Entered: November 27, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICRO LABS LIMITED and
MICRO LABS USA INC.,[1]
Petitioner,

v.

SANTEN PHARMCEUTICAL CO., LTD. and
ASAHI GLASS CO., LTD.,
Patent Owner.

Case IPR2017-01434
Patent 5,886,035

Before JO-ANNE M. KOKOSKI, CHRISTOPHER G. PAULRAJ, and DEBRA L. DENNETT, *Administrative Patent Judges.*

KOKOSKI, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] The Board terminated Petitioner's involvement without terminating the proceeding under 35 U.S.C. § 317(a). Paper 52.

I. INTRODUCTION

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–14 of U.S. Patent No. 5,886,035 ("the '035 patent," Ex. 1001) are unpatentable.

A. Procedural History

Micro Labs Limited and Micro Labs USA Inc. (collectively, "Petitioner") filed a Petition ("Pet.," Paper 1) to institute an *inter partes* review of claims 1–14 ("the challenged claims") of the '035 patent. Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (collectively, "Patent Owner") filed a Preliminary Response ("Prelim. Resp.," Paper 10). Pursuant to 35 U.S.C. § 314(a), we instituted an *inter partes* review based on the following grounds: (1) whether claims 1–14 are unpatentable under 35 U.S.C. § 103 as obvious over the combined teachings of Klimko,[2] Kishi,[3] and Ueno;[4] and (2) whether claims 1–14 are unpatentable under 35 U.S.C. § 103 as obvious over the combined teachings of Klimko, Kishi, Bezuglov

[2] EP 0 639 563 A2, published Feb. 22, 1995 (Ex. 1003).
[3] U.S. 5,292,754, issued March 8, 1994 (Ex. 1005).
[4] Japanese Unexamined Patent App. Pub. No. H7-70054, published Mar. 14, 1995 (Ex. 1006). We refer to "Ueno" as the English translation of the original reference.

1982[5] and/or Bezuglov 1986,[6] and Ueno. Paper 11 ("Dec. on Inst." or "Institution Decision"), 20.

After institution of trial, Patent Owner filed a Patent Owner Response ("PO Resp.," Paper 22) and Petitioner filed a Reply ("Reply," Paper 24). Petitioner relies on the Declaration and Supplemental Declaration of Mitchell A. deLong, Ph.D. ("deLong Declaration," Ex. 1027; "Supplemental deLong Declaration," Ex. 1031), and the Declaration and Supplemental Declaration of Aron D. Rose, M.D. ("Rose Declaration," Ex. 1028; "Supplemental Rose Declaration," Ex. 1032). Patent Owner relies on the Declaration and Supplemental Declaration of Timothy L. Macdonald, Ph.D. ("Macdonald Declaration," Ex. 2001; "Supplemental Macdonald Declaration," Ex. 2028), and the Declaration and Supplemental Declaration of Robert D. Fechtner, M.D. ("Fechtner Declaration," Ex. 2002; "Supplemental Fechtner Declaration," Ex. 2029). Patent Owner filed observations regarding the cross-examination of Dr. deLong (Paper 34) and Dr. Rose (Paper 35), and Petitioner filed responses (Papers 39, 40).

Petitioner filed a Motion to Exclude Exhibits 2023, 2027, 2034, 2038–2041, 2044, and 2047, and paragraphs 8–26 of the Supplemental Macdonald Declaration (Ex. 2028). Paper 30. Patent Owner filed an Opposition (Paper 37), and Petitioner filed a Reply (Paper 44). Patent Owner filed a Motion to Exclude Exhibits 1033–1035, 1037, 1038, 1040–1043, and 1045–

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[5] *Fluoroprostaglandins: A New Class of Bioactive Analogs of Natural Prostaglandins*, LIPIDS OF BIOLOGICAL MEMBRANES 88–91 (L. D. Bergelson, ed., 1982) (Ex. 1007). We refer to "Bezuglov 1982" as the English translation of the original reference.

[6] *Fluorodeoxy Prostaglandins, Synthesis and Perspectives*, PROSTAGLANDINS AND CARDIOVASCULAR DISEASES 191–200 (Takayuki Ozawa et. al. eds., 1986)

1060, certain paragraphs of the Supplemental deLong and Rose Declarations, and the testimony at lines 117:23–118:23 of the deposition of Dr. Rose (Ex. 2026). Paper 32. Petitioner filed an Opposition (Paper 41), and Patent Owner filed a Reply (Paper 45).

An oral hearing was held on September 6, 2018, and a transcript is included in the record. Paper 49 ("Tr.").

On November 27, 2018, with Board authorization, the parties filed a joint motion to terminate the instant proceeding. Papers 50, 51; Ex. 2066. In light of the advanced stage of the instant proceeding, the Board *granted-in-part* the motion to terminate. Paper 52. Consequently, the proceeding has been terminated with respect to Petitioner, but is not terminated with respect to Patent Owner. *Id.*

B. Related Proceedings

The parties indicate that the '035 patent is 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.

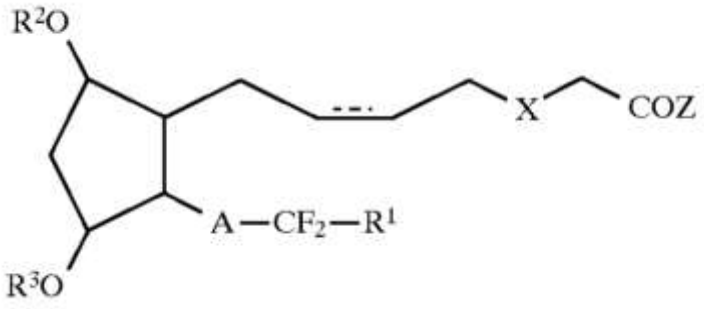
C. The '035 Patent

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-

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