UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICRO LABS LIMITED AND MICRO LABS USA INC.
Petitioners,

v.

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

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

PATENT OWNERS' OPPOSITION TO PETITIONERS' MOTION TO EXCLUDE EVIDENCE

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I. INTRODUCTION

Patent Owners Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (together, "Patent Owners") hereby oppose Petitioners Micro Labs Limited and Micro Labs USA Inc.'s (together, "Petitioners") Motion to Exclude Evidence (Paper No. 30) ("Motion"). For the reasons below, Petitioners' Motion should be denied in its entirety.

II. ARGUMENT

A. Ex. 2027 Should Not Be Excluded

Ex. 2027 is a court decision from the Canadian proceeding *Alcon Canada Inc. v. Apotex Inc.*, 2014 FC 699 (Fed. Ct. CA, 2014). In that proceeding, Petitioners' primary expert, Dr. deLong, testified on behalf of Alcon in support of the validity of a Canadian counterpart ("the Canadian '287 Patent") with an identical disclosure to Petitioners' main prior art reference in this case, Klimko (Ex. 1003). Ex. 2027 refers to and quotes Dr. deLong's testimony from the Canadian proceeding that flatly contradicts his opinions here.

In the present case, Dr. deLong opines that Compound C of Klimko, a **16-phenoxy** $PGF_{2\alpha}$ analog, would have been the lead compound for the development of tafluprost. *See e.g.*, Ex. 1027, ¶ 64. However, in the Canadian proceeding, Dr. deLong opined that there "was **very little, if any motive, to test any phenoxy prostaglandin compounds**, given the prior art information available." Ex. 2027, ¶

434 (emphasis added). Dr. deLong further testified that "[t]he teachings on **the use of any phenoxy were limited and not encouraging** (see prior discussion on Scjternschantz [sic] . . .)." *Id.*, ¶ 432 (emphasis added).

Furthermore, in the present case, Dr. deLong takes issue with the statement in Klimko that Compound C displays unacceptable hyperemia. Ex. 2025, 63:7-10. Yet, in the Canadian proceeding, Dr. deLong opined that Compound C "showed what appears to be **an unacceptable degree of hyperemia** and was **not advanced for further testing**." Ex. 2027, ¶ 314 (emphasis added). Moreover, Dr. deLong's testimony in the Canadian proceeding describing the previously reported data in Stjernschantz (Ex. 2017) regarding 16-phenoxy compounds (including Compound C) is inconsistent with his current position. In the Canadian proceeding, Dr. deLong testified that "[t]he closest compound exemplified is the 16-phenoxy, for which the **hyperemia testing provided relatively poor results**." Ex. 2027, ¶ 315 (emphasis added). He also testified that "the skilled person reading Stjernshantz would **likely not conclude that the 16-phenoxy** (or the structurally related compound fluprostenol) **does have an acceptable therapeutic profile** (separation of toward and untoward effects)." *Id.*

Dr. deLong also opines in this proceeding that Compound C exhibited a more favorable IOP profile than cloprostenol-IE (Compound A of Klimko) and fluprostenol-IE (Compound B of Klimko). Ex. 1027, ¶ 64. But again, Dr. deLong

said the opposite in the Canadian proceeding: "Dr. deLong agrees that **the IOP reductions** for the isopropyl esters of cloprostenol and fluprostenol **were comparable** to that of Compound C . . . ." Ex. 2027, ¶ 233 (emphasis added).

Importantly, Dr. deLong does not dispute that he made the above contradictory statements, nor does he contest their accuracy. Instead, he resorts to inaccurate distinctions between his prior and current testimony that only further call into question his credibility. Ex. 1031, ¶¶ 71-76. For example, Dr. deLong contends that his testimony in this case is not contradicted by his prior testimony because "the POSA in the Canadian proceeding would not have been aware of Kishi, one of the main prior art references in this matter, since it published after the priority date of the Canadian '287 patent [*i.e.*, August 3, 1993] in March 1994." Ex. 1031, ¶ 74; Reply (Paper 24) at 7. But a European Kishi counterpart ("the '856 Pub.") (Ex. 1004) with essentially identical disclosure to the Kishi reference asserted here (Ex. 1005) was published on **February 26, 1992**, well before the priority date of the Canadian '287 patent. In fact, Petitioners expressly admit in their own Petition that the '856 Pub. and Kishi "share nearly-identical disclosures and are **interchangeable** for purposes of Petitioners' Grounds 1 and 2 and reliance on Kishi therein." Petition (Paper 1) at 34 n. 6 (emphasis added).

Dr. deLong further contends that, "[b]y December 1996, the general view in the field was that the conjunctival hyperemia side effect was ***cosmetic in nature***

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