

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

**SUPPLEMENTAL DECLARATION OF
ROBERT D. FECHTNER, M.D.**

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I, Robert D. Fechtner, M.D., declare and state as follows:

I. INTRODUCTION

1. I am Professor and Chair of Ophthalmology at SUNY Upstate Medical University (Syracuse, NY).

2. I have been retained on behalf of Patent Owners Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (together, "Patent Owner") as an independent expert consultant in the above-referenced *inter partes* review ("IPR") proceeding, to provide information and opinions on the teachings of the prior art and the state of the art, as relevant to the issued claims of U.S. Patent No. 5,886,035 ("the '035 Patent"). Ex.1001.

3. I previously submitted a written declaration on these topics, which was filed as Ex.2002. I hereby incorporate my previous declaration into this declaration.

4. I understand from counsel that one issue in this proceeding is whether objective secondary considerations of nonobviousness (for example, commercial success, copying, unexpected results, long-felt but unmet need, and failure of others) support the nonobviousness of the claims of the '035 Patent. I have been asked to opine as to whether there was a long-felt but unmet need for tafluprost and whether there has been a failure of others to fill that long-felt but unmet need.

5. My opinions in this declaration are based on documents I have reviewed in connection with this proceeding, and are further informed by my knowledge and experience, including my decades of experience with glaucoma research, diagnosis, treatment and prevention. An updated list of the documents and materials that I considered in connection with the development of my opinions set forth in this (and my previous) declaration is attached hereto as Exhibit B.

II. LONG-FELT BUT UNMET NEED

6. In my opinion, as of December 26, 1996, tafluprost's unique receptor profile and associated properties filled a previously long-felt but unmet need for an effective prostaglandin analog that can be tolerated by patients unable to tolerate other prostaglandin analogs.

7. The therapeutic profile of prostaglandin analogs (and other drugs) are typically defined in large clinical trials, which provide average results for the population that was studied. Those clinical trials also typically report non-responders and discontinuations for tolerability issues. In the context of prescribing prostaglandin analogs to my patients, however, it is impossible to predict in advance whether any given patient will be a responder or non-responder, find the medication tolerable or intolerable, or be anywhere in between in either of those respects. In other words, it is impossible to predict in advance (1) whether and to what degree IOP will be lowered, and (2) the accompanying side effects. In

my opinion, the addition of tafluprost to our armamentarium provides better outcomes and improved quality of life for patients that are prescribed it.

8. Despite the lower cost of generic latanoprost, I still prescribe Zioptan® (branded tafluprost in the US) to many of my patients, and in my opinions, those patients are benefitting from the unique benefits of Zioptan®/tafluprost. In my experience, Zioptan®/tafluprost provides prostaglandin efficacy (understood in the field as 6-8 mm Hg lowering of IOP) and superior tolerability in those patients for whom I have selected it. For example, many of my patients have ocular surface disease or a history of adverse effects with other glaucoma drugs (including prostaglandin analogs): for those patients, I tend to prescribe Zioptan®/tafluprost, which is better tolerated and facilitates compliance, and therefore better preserves the patients' quality of life.

9. The only other prostaglandin analog available outside the US as of December 26, 1996 was isopropyl unoprostone, which has been reported to be well-tolerated. But, it requires twice-daily dosing, which is undesirable compared to the once-daily dosing of the other commercially-available prostaglandin analogs, including tafluprost. *Compare* Ex.2042 (Rescula®/isopropyl unoprostone label), 1 with Ex.2032 (Zioptan®/tafluprost label), 1; Ex.2037 (Xalatan®/latanoprost label), 1; Ex.2038 (Lumigan®/bimatoprost 0.03% label), 1;

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