IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

In the *Inter Partes* Review (IPR) of U.S. Patent No. 5,886,035

DECLARATION OF MITCHELL A. DELONG, PH.D.

I, Mitchell A. deLong, Ph.D., declare as follows:

I. INTRODUCTION AND BACKGROUND

A. Qualifications

1. I am Vice President (Chemistry R&D) of Aerie Pharmaceuticals and an Adjunct Professor in the Department of Chemistry at Duke University. I am an expert in synthetic organic and medicinal chemistry with more than 25 years of experience in the chemical arts.

2. I earned my Ph.D. in Synthetic Organic and Medicinal Chemistry with a concentration in Cancer Biology from Stanford University in 1991.

3. I also earned in 1982 a multidisciplinary Bachelor of Science degree in Biology and Chemistry from Michigan State University-Lyman Briggs College during which I was a 4-year National Merit Scholar.

4. I have led research and development teams including a team at the

Duke Eye Center at Duke University that has resulted in three spinoff companies. In 2006, one of the companies filed an Investigational New Drug Application (IND) to advance a novel prostaglandin prodrug named AR-102 that subsequently completed Phase 2 clinical trials.

5. My expertise and experience in organic synthetic and medicinal chemistry include research and development of analogues of naturally occurring prostaglandins. I have synthesized prostaglandin analogues and tested them in various animal models to study their potential for use in treating glaucoma and ocular hypertension.

6. I am named as inventor on 45 issued patents and 85 published patent applications in the United States. A number of these patents and published applications relate to the subject matter of prostaglandin analogues, their preparation and their use in the treatment of glaucoma and ocular hypertension.

7. I have published research in several peer-reviewed academic journals and also given numerous invited talks and scientific presentations on a variety of subjects including prostaglandins and glaucoma treatments.

8. My curriculum vitae provided as Appendix B contains additional details relating to my background including experience and publications.

B. Scope of Work

9. I have been retained by the law firm Pillsbury Winthrop Shaw Pittman

LLP (“Pillsbury”) on behalf of Petitioners Micro Labs Limited and Micro Labs USA Inc. ("Micro") to consult in connection with this matter. My compensation on this matter is $250 per hour and it is neither dependent on the substance of my testimony nor the outcome of this matter.

10. For purposes this declaration, I have been asked to assess whether a person of ordinary skill in the art (“POSA”), which I define later in my declaration, would have found the subject matter claimed in the claims of U.S. Patent No. 5,886,035 (“the ’035 patent,” Ex. 1001) obvious in view of the prior art and the general knowledge of the POSA.

11. In relation to the above, I was asked to review and discuss in my declaration the problems to be solved by and also the understandings and motivations of the POSA researching and developing prostaglandin analogues that could be used for treatment and/or management of elevated intraocular pressure (IOP)/ocular hypertension and glaucoma. I was asked to discuss the preceding in view of the prior art that I reviewed and to assess what would have been the POSA’s starting point for a lead compound and what modifications in view of the prior art teachings the POSA would have made to the lead compound.

12. This declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. I reserve the right to respond as needed to any additional information or any response to my

declaration.

13. I and others working under my direction prepared and referenced the exhibits I reviewed and relied upon for my declaration. The entirety of my declaration, including exhibits and referenced materials, supplies the basis for my analysis and conclusions. The organizational structure of the declaration is for convenience.

14. To the extent that facts and other considerations overlap, I generally discuss such information and issues related to them only once for the sake of brevity and those reviewing my declaration should refer to my earlier discussions in the declaration as needed. Neither the specific order in which each issue is addressed nor the organization of my declaration or exhibits affects the ultimate outcome of my analysis and conclusion.

C. U.S. Patent No. 5,886,035 (Ex. 1001)

15. I have reviewed the ’035 patent in that I have read and familiarized myself with it.

16. I understand based on my review that the ’035 patent has 14 claims and is directed to fluorine-containing prostaglandin derivatives, specifically derivatives having two fluorine atoms at the C-15 position, their alkyl esters, or their salts, and to medicines containing one of these compounds as an active ingredient. These compounds are intended for use in medicine to treat eye diseases

or conditions, such as glaucoma and ocular hypertension.

17. I understand that the '035 patent is assigned to Patent Owners Santen Pharmaceuticals Co., Ltd. ("Santen") and Asahi Glass Co., Ltd. ("Asahi") and is alleged to cover the commercially-available drug product ZIOPTAN®, which is an ophthalmic solution containing the active compound tafluprost. I further understand that the '035 patent is listed in the FDA's Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations in connection with Oak Pharmaceuticals, Inc.'s ("Oak") New Drug Application (NDA) for ZIOPTAN®. (Patent and Exclusivity for N202514, Ex. 1017). I understand that the claims of the '035 patent is alleged to cover tafluprost and medicines that contains tafluprost.

18. I understand that Micro is being sued for patent infringement by Oak, Santen and Asahi on claims 1-14 of the '035 patent in the United States District Court for the District of Delaware. I am aware that the basis for this lawsuit is a technical act of infringement based on Micro's filing of an Abbreviated New Drug Application seeking FDA approval to commercially market Micro's proposed generic tafluprost product prior to the expiration of the '035 patent. I understand that this case has been docketed as *Santen Pharmaceutical Co., Ltd., Asahi Glass Co., Ltd. and Oak Pharmaceuticals, Inc. v. Micro Labs limited and Micro Labs USA Inc.*, Case No. 16-cv-00353 (D. Del. 2016).

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