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 ARON D. ROSE, M.D.

I, Aron D. Rose, M.D., declare as follows:

I. INTRODUCTION AND BACKGROUND QUALIFICATIONS

A. Qualifications

1. I am a practicing ophthalmologist and member of The Eye Care Group specializing in complex cataract surgery and glaucoma. I have privileges as an attending physician and surgeon at Yale New Haven Hospital and Saint Mary's Hospital in Connecticut.

2. In addition to my ophthalmology practice, I teach at Yale University as Associate Clinical Professor in the Department of Ophthalmology and Visual Sciences at the School of Medicine and as Associate Clinical Professor in the Graduate Entry Program in Nursing at the School of Nursing. I was also the previous Director of Residency Training in the Department of Ophthalmology and Visual Sciences at the Yale School of Medicine. I am also an Associate

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Clinical Professor in the Department of Medical Sciences at the Frank H. Netter MD School of Medicine at Quinnipiac University. I am also a member of the Connecticut Glaucoma Society.

3. I earned my M.D. from New York Medical College in 1985 following a B.A. from Brown University in 1980.

4. I have authored or co-authored 17 peer-reviewed publications, have served as an investigator in 20 studies dealing with the treatment of glaucoma and ocular hypertension, and have presented numerous lectures on these topics.

5. My curriculum vitae, provided in Appendix B, contains more details on my background, experience, publications, and prior expert testimony.

B. Scope of Work

6. I have been retained by the law firm Pillsbury Winthrop Shaw Pittman LLP ("Pillsbury Winthrop") on behalf of Petitioners Micro Labs Limited and Micro Labs USA Inc. (together "Micro") in connection with this matter. I am being compensated at a rate of $500 per hour for my work in connection with my consultation for this declaration. My compensation is neither dependent on the substance of my testimony and opinions in this matter nor is it dependent on the outcome of this matter.

7. For purposes of preparing my declaration, I have examined U.S. Patent No. 5,886,035 ("the '035 patent," Ex. 1001) and the other prior art

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materials identified below. I understand that the contents of declaration will be relied on in collaboration with a medicinal chemist to evaluate whether the subject matter claimed in the ’035 patent would have been obvious to a person of ordinary skill in the art as defined below. My understanding is that my expertise will be relied on insofar as it relates to the development of prostaglandin analogues for the treatment and/or management of elevated intraocular pressure (IOP) and glaucoma for all relevant time periods including the period that is just prior to the time of the alleged invention that is the subject of the ’035 patent.

8. This declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. I and others either working with me or under my direction prepared the exhibits of the materials that I reviewed and relied upon in my declaration. The entirety of my declaration, including the exhibits and referenced materials, supplies the basis for my analysis and conclusions. The organizational structure of the declaration is for convenience. I reserve the right to supplement my opinions or respond as needed to opinions and assertions made by others in this matter.

9. To the extent that facts and other considerations overlap, I generally discuss such issues only once for the sake of brevity. Neither the specific order in which each issue is addressed nor the organization of my declaration or exhibits affects the ultimate outcome of my opinions.

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

10. I have read the '035 patent, which I have been informed allegedly covers the commercially-available product ZIOPTAN.® I am aware that ZIOPTAN® is an ophthalmic solution containing tafluprost marketed by Oak Pharmaceuticals, Inc. ("Oak").

11. I have been informed and understand that Oak is the holder of the New Drug Application for ZIOPTAN® and the '035 patent is listed in the FDA's Electronic Orange Book in connection with this product. I understand that the '035 patent is assigned to patent owners Santen Pharmaceuticals Co., Ltd. ("Santen") and Asahi Glass Co., Ltd. ("Asahi").

12. I have been informed and understand that the claims of the '035 patent are directed to fluorine-containing prostaglandin derivatives, specifically derivatives having two fluorine (F) atoms at the C-15 position, their alkyl esters, or their salts, and to medicines containing one of these compounds as an active ingredient. I also understand that the compounds covered by the '035 patent are alleged to be useful in medicine to treat an eye disease such as glaucoma and ocular hypertension.

13. I understand that Oak, Santen and Asahi have filed a lawsuit for patent infringement against Micro in connection with Micro's filing of Abbreviated New Drug Application No. 209051 that seeks FDA approval to

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commercially market a generic tafluprost product. I understand that this lawsuit has been stylized *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).

II. BACKGROUND

A. Legal Understanding

14. My opinions as stated herein are predicated on my knowledge and expertise.

15. It is my understanding that each of the claims of the '035 patent define the scope of the invention that is entitled to protection. I understand that in assessing the claims of the '035 patent for purposes of this declaration, they are to be construed with the broadest reasonable interpretation. It is also my understanding that such interpretation includes giving the plain and ordinary meaning to the claim language and as informed by what I understand to be the patent specification. It is my opinion in reviewing the claims that there are no claim terms that require special interpretation beyond their plain and ordinary meaning.

16. I understand that a patent claim is unpatentable as obvious if the subject matter of the claim as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention.

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