

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.

Inter Partes Review No. IPR2017-01434
U.S. Patent No. 5,886,035

SUPPLEMENTAL DECLARATION OF ARON D. ROSE, M.D.

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

I. INTRODUCTION AND BACKGROUND QUALIFICATIONS

1. 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. (collectively “Micro”) in connection with the captioned matter.

2. I previously submitted a declaration in connection with this matter, marked Micro Labs Exhibit 1028, on May 12, 2017. My background and qualifications are summarized in my May 12, 2017 Declaration. I also provided a then-current copy of my curriculum vitae as Appendix B. The most current version of my curriculum vitae is appended to the present Declaration as Appendix B.

3. I understand that Micro filed a petition with the United States Patent and Trademark Office (“USPTO”) requesting that the USPTO institute a proceeding to adjudicate the validity of U.S. Patent No. 5,886,035 (“the ’035 patent”). I further understand that Santen Pharmaceutical Co., Ltd. and Asahi Glass Co., Ltd. (collectively, “Patent Owners”) filed a preliminary response opposing Micro’s petition. I further understand that the USPTO, having considered Micro’s petition and Patent Owners’ preliminary response, determined that Petitioner demonstrates a reasonable likelihood of showing that claims 1–14

would have been obvious over the combined teachings of Klimko, Kishi, and Ueno.” (Paper No. 11, p. 19.)

II. SCOPE OF WORK

4. As set forth in my May 12, 2017 Declaration, I am being compensated at a rate of \$500 per hour for my work in connection with my work on this matter. My compensation is not dependent on the substance of my testimony, my opinion on any issue, or the outcome of this matter.

5. I understand that the contents of my Declaration will be relied on in conjunction with a medicinal chemist to evaluate whether the subject matter claimed in the '035 patent would have been obvious to the Person of Ordinary Skill in the Art as of December 1996 (“POSA”), which is defined in my May 12, 2017 declaration (Ex. 1028).

6. For the purposes of this Declaration, I have been asked to review the original and supplemental declarations of Patent Owners’ experts, Exs. 2001, 2002, 2028, and 2029. I have been asked to consider the opinions and analysis expressed therein, including as it relates to: 1) whether Klimko “teaches away” from selecting Compound C as a lead compound; 2) whether the POSA would have been dissuaded or otherwise led away from selecting Compound C as a lead compound due to concerns about a purported “initial rise” in IOP and/or hyperemia; and 3) whether the following “secondary considerations” support nonobviousness of the

claims of the '035 patent: commercial success/copying and long-felt but unmet need.

7. In preparing this Declaration, I reviewed and considered the declarations submitted by Dr. Macdonald, marked as Exhibits 2001 and 2028, as well as the materials referenced therein, and the declarations submitted by Dr. Fechtner, marked as Exhibits 2002 and 2029, as well as the materials referenced therein. Their declarations did not change my opinions. As I explain further below, their declarations contain a number of misleading statements, omissions, and outright errors.

8. Further, in addition to the materials I considered for the purpose of preparing the opinions and analysis contained in my May 12, 2017 Declaration, and the materials referred to in paragraph 7 above, I have reviewed and considered those materials listed in Appendix A to this Declaration, which is an updated version of Appendix to my May 12, 2017 Declaration.

9. This Declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. Either myself or others working with me or under my direction prepared the exhibits of the materials that I either reviewed, considered or otherwise relied upon in the present 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.

III. LEGAL STANDARDS

10. In addition to the legal standards set forth in my May 12, 2017 Declaration, counsel has informed me of the following legal standards, which I also apply for the purpose of the present Declaration.

11. I am informed and understand that evidence of “secondary considerations” can be relevant to determining whether a claim is obvious.

12. I am informed and understand that evidence of secondary considerations of nonobviousness cannot overcome a clear case of obviousness.

13. I am informed and understand that there must be a nexus between the merits of the claimed subject matter and any alleged secondary consideration.

14. I am informed and understand that any alleged secondary considerations of nonobviousness must be commensurate in scope with the claimed invention. In other words, for example, evidence of superior properties for one claimed compound is not necessarily sufficient to support the non-obviousness of all the other claimed compounds.

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