

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Biocon Pharma Limited
Petitioner,

v.

Novartis Pharmaceuticals Corporation
Patent Owner.

U.S. Patent No. 8,101,659 to Ksander et al.

Issue Date: January 24, 2012

Title: Methods of Treatment and Pharmaceutical Composition

Inter Partes Review No.: IPR2020-01263

Declaration and Curriculum Vitae of Y. W. Francis Lam, Pharm.D., FCCP

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U.S. Patent and Trademark Office

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a) Claim 157

b) Dependent Claims 2-4.....79

3. Ground 2: Claims 1-4 Would Have Been Obvious over the PDR In View of the '996 Patent, Gomez-Monterrey, and EP'07286

c) Claim 186

d) Dependent Claims 2-4.....97

4. No Secondary Considerations of Nonobviousness101

a) No Unexpected Results101

I, Y. W. Francis Lam, Pharm.D., FCCP, do hereby declare and state as follows:

1. I have been asked to provide testimony as to what one of ordinary skill in the art would have understood with respect to the patent at issue and various prior art discussed herein. I provide this testimony below:

1. INTRODUCTION

2. I am over the age of eighteen (18) and otherwise competent to make this declaration.

3. I have been retained as an expert witness on behalf of Petitioner Biocon Pharma Limited for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$500 per hour. My compensation is in no way dependent on the outcome of this IPR.

4. I understand that the petition for IPR involves U.S. Patent No. 8,101,659 (“the ’659 patent”) (EX1001).

5. The ’659 patent names Gary M. Ksander and Randy L. Webb as the purported inventors.

Declaration of Prof. Y. W. Francis Lam

6. For the purposes of this declaration, I have been told to assume the relevant priority date of the '659 patent is January 17, 2002¹—the filing date of U.S. Provisional Application No. 60/349,660. I further understand that the '659 patent is assigned to Novartis Pharmaceuticals Corporation (“Novartis,” “Patentee,” or “Patent Owner”).

7. As explained below, it is my opinion that Claims 1-4 of the '659 patent would have been obvious to the skilled artisan as of the time of the priority date of the '659 patent. Therefore, these claims are invalid.

2. MY EXPERIENCE AND QUALIFICATIONS

8. I am an expert in the field of pharmacology, pharmaceutical sciences and pharmacokinetics. Specifically, I specialize in pharmacology, pharmacokinetics, drug metabolism, and clinical pharmacology, particularly the medical aspects of drugs acting on biological systems, such as the renin-angiotensin-aldosterone system (RAAS), and I have been an expert in this field since prior to 2002. I have relied upon my training, knowledge, and experience in the relevant art to form my opinions.

¹ I have not been asked to analyze whether this is indeed the correct priority date but rather assume that it is for the purposes of my declaration. However, should this become an issue during the proceeding, I may be called upon to offer my opinion.

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