

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 of Y. W. Francis Lam, Pharm.D., FCCP

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

Table of Contents

1.	INTRODUCTION.....	1
2.	MY EXPERIENCE AND QUALIFICATIONS.....	2
3.	LIST OF MATERIALS CONSIDERED.....	9
4.	LEGAL STANDARD.....	12
A.	Obviousness.....	12
5.	PERSON OF ORDINARY SKILL IN THE ART (“POSA”).....	16
6.	BACKGROUND OF RELEVANT TECHNICAL CONCEPTS.....	18
A.	Angiotensin II and NEP Inhibition.....	18
7.	THE ’659 PATENT.....	28
8.	CLAIM CONSTRUCTION.....	32
9.	OBVIOUSNESS.....	32
A.	Claims 1-4 Would Have Been Obvious.....	33
1.	The Scope and Content of the Prior Art.....	33
a)	EP’072.....	33
b)	Trippodo.....	37
c)	Shetty.....	40
d)	Gomez-Monterrey.....	44
e)	Ksander.....	47
f)	The ’996 Patent.....	53
g)	PDR.....	56
2.	Ground 1: Claims 1-4 Would Have Been Obvious over EP’072, Shetty, Gomez-Monterrey, and Ksander.....	57

Declaration of Prof. Y. W. Francis Lam

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.