

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner

Case IPR2017-01053
Patent 8,268,299

DECLARATION OF GEORGE G. ZHANEL, Ph.D.

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 C. The POSA Would Have Expected that Compositions
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I, George G. Zhanel, hereby declare as follows:

I. Introduction

1. I am over the age of eighteen and am otherwise competent to make this declaration.

2. I understand that the Patent Trial and Appeal Board has granted Argentum Pharmaceuticals LLC's petition to institute this *Inter Partes* Review ("IPR") regarding claims 1-28 of United States Patent No. 8,268,299 (the "'299 patent") on obviousness grounds.

A. Background and Qualifications

3. I am currently a Professor in the Department of Medical Microbiology/Infectious Diseases, Max Rady College of Medicine, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, Canada.

4. I received a Ph.D. in Medical Microbiology from the University of Manitoba in 1994 and a Doctor of Pharmacy from the University of Minnesota in 1986.

5. For approximately the last 30 years, the focus of my work has been antimicrobials and agents with antimicrobial activity.

6. I am currently the Chair of the Canadian Antimicrobial Resistance Alliance (CARA) in the Max Rady College of Medicine at the University of Manitoba. I am also the Coordinator of the antimicrobial resistance program in the

Section of Infection Control and Prevention, Department of Internal Medicine at the Health Sciences Centre, Winnipeg, Canada.

7. The focus of my research is the study of antimicrobial agents and agents with antimicrobial activity in the treatment and prevention of infectious diseases. Agents with antimicrobial activity include traditional antibiotics used in humans and animals, as well as antiseptics, preservatives, disinfectants, and sterilizers. I gave my first presentation on antimicrobials in 1985 while working toward my Doctor of Pharmacy. In addition, as early as 1985, I began advising clinicians regarding the use and optimization of antimicrobials for the treatment and prevention of infectious diseases, and I began teaching about antimicrobials in 1987. The subject of my doctoral thesis in Medical Microbiology, published in 1994, was “Cellular and Molecular Evaluation of Fluoroquinolone Resistance in *Pseudomonas aeruginosa*.”

8. By virtue of my education and experience, I am familiar with microorganisms that are likely to grow in liquid pharmaceutical compositions such as ophthalmic solutions, the preservative efficacy standards (“PET”) that pharmaceutical products must meet so as to minimize or inhibit growth of such microorganisms, the testing and evaluation of antimicrobial agents, and the testing and evaluation of the preservative efficacy of pharmaceutical formulations. As

part of my education and experience, I have also prepared numerous pharmaceutical formulations, including topical ophthalmic formulations.

9. I currently teach medical students at the University of Manitoba in the first, second, third and fourth years of the Medical curriculum. I also teach internal medicine residents and medical microbiology/infectious diseases postdoctoral fellows. In addition, I teach physician assistants, nurse practitioners, and Masters and Doctoral students in both Medical Microbiology and Clinical Pharmacology, as well as undergraduate students in Science, Pharmacy, Nursing and Medical Technology.

10. My work on antimicrobials has led me to serve as a consultant (through advisory boards or otherwise) to many pharmaceutical/biotech companies. These companies include the following companies and/or their affiliates: Abbott, Achaogen, Affinium, Allergan, Astellas, AstraZeneca, Avir, Bayer, Cangene, Cerexa/Forest Labs, Cubist, GlaxoSmithKline, Janssen Ortho/Ortho McNeil, Kane BioTech, Merck, Novexel, Optimer, Paladin Labs, Paratek, Pfizer, Procter & Gamble, Sanofi-Aventis, Sunovion, The Medicines Co., Tetrphase, Theravance, Triton, Trius, Verity, and Zoetis. As part of my research and consultancy role for these companies, I am routinely called on to provide advice concerning the potential indications for antimicrobials based on a compound's properties, as well as to make comparative evaluations among

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