

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX CORP.,  
Petitioner

v.

ALCON RESEARCH, LTD.,  
Patent Owner.

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Case IPR2013-00428  
U.S. Patent No. 8,268,299 B2

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**DECLARATION OF GEORGE G. ZHANEL, Ph.D.**

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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 Apotex'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, Faculty of Medicine, 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 25 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) and on the Faculty of Medicine at the University of Manitoba. I also am the Coordinator of the antimicrobial resistance program in the

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

7. The focus of my research is the study of antimicrobial agents in the treatment and prevention of infectious diseases. 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, submitted 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 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, Apotex, Arpida, Astellas, AstraZeneca, Bayer, Cangene, Cerexa, Cubist, Forest Labs, GlaxoSmithKline, Janssen Ortho/Ortho McNeil, Kane BioTech, Merck, Micrologix, Novexel, Optimer, Oryx, Pfizer, Procter & Gamble, Sanofi-Aventis, Sepracor, Sunovion, TaiGen, The Medicines Co., Theravance, Triton, and Trius. 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 antimicrobials. Specific topics on which I am asked to advise include comparative mechanism of action and resistance, *in-vitro* activity and factors that influence antimicrobial activity, pharmacokinetics and pharmacodynamics, animal studies including efficacy and toxicity, and clinical uses including indications, adverse effects in

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