

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner.

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

DECLARATION OF SOUMYAJIT MAJUMDAR, Ph.D.

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I, Soumyajit Majumdar, Ph.D., hereby declare as follows:

I. INTRODUCTION

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

2. I have been informed by counsel for Alcon Research, Ltd. (“Alcon”) that the Patent Trial and Appeal Board has granted the petition of Apotex Corp. (“Apotex”) to institute this Inter Partes Review (“IPR”) regarding the purported obviousness of claims 1-28 of U.S. Patent No. 8,268,299 (the “’299 patent”). I understand from counsel that the following are the four grounds of obviousness at issue:

Ground 1: Obviousness of claims 1, 2, 4, 8, 16, 17, and 20 over World Intellectual Property Organization International Patent Application Number 2005/097067 A1 (“Xia”), APO 1003, and United States Patent No. 6,143,799 (“Chowhan”), APO 1004;

Ground 2: Obviousness of claims 1-4, 8, 9, and 13-21 over Xia, Chowhan, and Gadd *et al.*, “Microorganisms and Heavy Metal Toxicity,” *Microbial Ecology*, 4:303-317 (1978) (“Gadd”), APO 1005;

Ground 3: Obviousness of claims 5-7 and 28 over Xia, Chowhan, and the FDA Approved Drug Label for “TRAVATAN[®] (travoprost ophthalmic solution) 0.004% sterile” (“TRAVATAN[®] Label”), APO 1006; and

Ground 4: Obviousness of claims 10-12 and 22-28 over Xia, Chowhan, Gadd, and the TRAVATAN[®] Label.

3. I have been retained as an expert witness to opine as to various aspects of the compositions claimed in the '299 patent, including whether those compositions would have been obvious from the perspective of one of ordinary skill in the art (“POSA”) as of the priority date, which I have been asked to assume by counsel to be September 21, 2006 (“priority date”).

4. I have been informed by counsel for Alcon that an obviousness analysis involves a review of the scope and content of the prior art, the differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and “objective indicia of non-obviousness,” such as long-felt need and commercial success. In particular, I have been advised that, for an invention to be regarded as “obvious,” the POSA must have had a reason to modify the prior art or to combine one or more prior art references in a manner that would yield the claimed invention. I have also been informed that, for a claim to be obvious, the POSA must have a reasonable expectation of success with respect to the claimed invention. I have analyzed each of those questions, except that I understand that other experts for Alcon will address objective evidence of nonobviousness.

A. Background and Qualifications

5. I am an expert in the area of drug delivery, formulation, and disposition, in particular ocular drug delivery, formulation, and disposition. I have more than twelve years of experience, in addition to my graduate studies and research, in the fields of topical ophthalmic formulation, ocular penetration, drug delivery, and disposition. I have performed and become familiar with numerous experiments involving stability, solubility, ionic interactions within ophthalmic formulations, complex formation, and the influence of formulation on preservative efficacy. My recent research activities have focused primarily on the development of drug delivery methods to enhance ocular bioavailability of poorly permeating compounds. In this research, I focus on, among other things, biopharmaceutical and pharmacokinetic considerations, and formulation design. My ocular drug delivery research is and has been supported by funding received from the National Eye Institute and National Institute of General Medical Sciences of the National Institutes of Health.

6. Based on my education, background, experience, and expertise, I am qualified to provide an opinion as to what a person of ordinary skill in the art would have understood, known or concluded as of the priority date.

7. I am currently an Associate Professor of Pharmaceutics at the University of Mississippi in Oxford, Mississippi. In addition to my position at the

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