

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 SOUMYAJIT MAJUMDAR, Ph.D.**

**TABLE OF CONTENTS**

I. Introduction.....4

A. Background and Qualifications .....6

B. The Person of Ordinary Skill in the Art .....10

C. Construction of Claims.....11

D. Background Regarding Calculations.....11

II. The Disclosures in Schneider, Xia, and Chowhan Would Not Have Rendered Obvious the Invention Claimed in the '299 Patent. ....14

A. Schneider .....14

B. Xia .....15

C. Chowhan.....19

D. Because Xia Solved the Problem Presented, the POSA Would Have Had No Reason to Combine Schneider with Xia .....21

E. Even Assuming the POSA Combined Schneider with Xia, the POSA Would Not Have Had Reason to Practice the Claimed Invention.....24

1. The POSA would reasonably expect that the combined Schneider/Xia formulation would pass preservative efficacy testing. ....24

2. The POSA would not have been motivated to reduce the concentration of zinc below the levels disclosed in Xia's Examples to the levels claimed in the '299 patent. ....28

3. Even if the POSA were to decrease the concentration of zinc below 0.48 mM, the POSA would have included a conventional preservative in the solution. ....30

4. Even if the POSA were to decrease the concentration of zinc below that in Xia's Example 18, the POSA would

not have been motivated to modify the Schneider/Xia  
formulation with Chowhan .....34

F. Limiting the Concentration of Anionic Species Would Not  
Have Been Obvious to the POSA. ....38

G. The '299 Patent's Propylene Glycol and Sorbitol Limitations  
Would Not Have Been Obvious to the POSA. ....44

H. The pH Limitations in the '299 Patent Would Not Have Been  
Obvious to the POSA. ....52

III. The Disclosures in Schneider, Xia and Chowhan Combined with the  
Disclosures in Gadd Would Not Have Rendered Obvious the  
Invention Claimed in the '299 Patent. ....56

IV. The Disclosures in Schneider, Xia and Chowhan Combined with the  
Disclosures in the TRAVATAN® Label Would Not Have Rendered  
Obvious the Invention Claimed in the '299 Patent. ....61

V. The Disclosures in Schneider, Xia, Chowhan, Gadd and the  
TRAVATAN® Label Combined Would Not Have Rendered Obvious  
the Invention Claimed in the '299 Patent. ....62

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 Argentum Pharmaceuticals LLC (“Argentum”) 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”), Ex. 1003, United States Patent No. 6,011,062 (“Schneider”), Ex. 1007, and United States Patent No. 6,143,799 (“Chowhan”), Ex. 1004;

**Ground 2:** Obviousness of claim 28 over Xia, Schneider, Chowhan, and the FDA Approved Drug Label for “TRAVATAN® (travoprost ophthalmic solution) 0.004% sterile” (“TRAVATAN® Label”), Ex. 1006;

**Ground 3:** Obviousness of claims 1–23, 25, and 26 over Xia, Schneider, Chowhan, and Gadd *et al.*, “Microorganisms and Heavy Metal Toxicity,” *Microbial Ecology*, 4:303–317 (1978) (“Gadd”), Ex. 1005;

**Ground 4:** Obviousness of claims 24, 27, and 28 over Xia, Schneider, 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

# 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.