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 STEPHEN SHANNON, MBA, Ph.D.

I, Stephen Shannon, MBA, Ph.D., hereby declare as follows:

I. INTRODUCTION

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

2. I have been asked by counsel to provide a declaration attesting to how certain data in the specification of U.S. Patent No. 8,268,299 (the "'299 patent") related to preservative efficacy testing ("PET"), sometimes called antimicrobial effectiveness testing ("AET"), were generated.

II. BACKGROUND AND QUALIFICATIONS

3. I am currently on the Alcon R&D Microbiology Leadership Team, and, as such, I am responsible for the management and oversight of preservative efficacy testing conducted at Alcon.

4. Prior to assuming my current position in 2012, I was part of the R&D Microbiology Management Team, which included managing the PET working group at Alcon. I held that position for more than six years.

5. I have been involved with PET at Alcon since I began my employment with the company in 1995.

6. I received a Ph.D. in Quantitative Biology (Microbiology) from The University of Texas in 2006. I also received an MBA (Information Systems) from

The University of Texas in 2001, and a Bachelors of Science degree (Marine Biology) from Texas A&M University in 1991.

III. DATA IN THE '299 PATENT SPECIFICATION

7. As a Manager in the R&D Microbiology Department, I was involved in the preservative efficacy testing the R&D Microbiology Department conducted of certain formulations described in the specification of the '299 patent, including the Examples discussed herein. As such, I have first-hand knowledge of the testing described below.

8. Preservative efficacy refers to the ability of a formulation to maintain acceptable levels of antimicrobial activity. The requirements for preservative efficacy are spelled out in the United States Pharmacopeia ("USP"), or in one of its various foreign counterparts, such as the European Pharmacopeia ("Ph. Eur.").

9. At Alcon, the R&D Microbiology Department performs PET on formulations prepared by another group; the R&D Microbiology Department does not prepare the formulations to be tested. Rather, a separate group prepares the formulations and provides them to the R&D Microbiology Department for testing.

10. I am familiar with the way in which Alcon keeps its records related to PET. In its usual and ordinary course of business, Alcon issues numbered laboratory notebooks to scientists, who use the notebooks to record their work relating to the testing of formulations, including PET. Notebooks may relate to

more than one project. Each notebook page should generally identify the particular notebook number and the page number, the title of the experiment and the project number.

11. Alcon also maintains an electronic database of PET results. This database is called the Laboratory Information Management System, referred to as LIMS.

12. Alcon maintains laboratory notebooks and LIMS reports in the usual and ordinary course of its business, and did so during the time of the PET discussed herein of certain Example formulations described in the '299 patent.

13. Examples D – F, L – N, and U – W as set forth in the specification of the '299 patent describe formulations which were provided to the Microbiology Department for PET. The '299 patent identifies the particular formulation by listing the formulation identification number ("FID") and lot number for each formulation. I am familiar with the PET of the particular formulations described in Examples D – F, L – N, and U – W of the '299 patent, which was conducted by the scientists in the Microbiology Department.

14. Each formulation described in Examples D – F, L – N, and U – W of the '299 patent was tested according to standard practices used within the field of microbiology. The formulations in Examples D – F and L – N were subject to an organism challenge test, according to the methods described in the USP 24 for

category 1A products (which includes ophthalmic products). In an organism challenge test, a sample of a particular formulation is inoculated with known levels of different types of bacteria and fungi. The samples are then evaluated at intervals of 7, 14 and 28 days to determine if the preservative system in the formulation was capable of killing, or inhibiting the propagation of, the organisms introduced into the formulation.

15. The amount of antimicrobial activity at the particular time intervals is used to assess whether the formulation satisfies USP 24 requirements. In general, for bacteria, formulations must have sufficient anti-bacterial activity to reduce an initial inoculum of approximately 10^5 to 10^6 bacteria by one log (i.e., a 90% reduction in the population) over a period of seven days and by three logs (i.e., a 99.9% reduction in the population) over a period of fourteen days, and must also show no increase in the microorganism population following the conclusion of the 14-day period. For fungi, the formulations must maintain stasis (i.e., no growth) relative to the population of the initial inoculum over the entire 28-day test period. These USP 24 standards are substantially the same as the requirements in the subsequent versions of the USP up through and including USP 27.

16. The formulations described in Examples U – W were tested using a modified PET screen test. The test method itself is similar to that described in the preceding paragraphs, but different time intervals are applied during the testing.

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