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 BHAGWATI P. KABRA, Ph.D.

I, Bhagwati P. Kabra, 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 am the first named inventor on U.S. Patent No. 8,268,299 (the "'299 patent"). I have been asked to provide a declaration attesting to how certain data in the specification of the '299 patent were generated.

II. BACKGROUND AND QUALIFICATIONS

3. I received a B.S. in Chemical Engineering in 1986 from the Department of Chemical Technology, University of Bombay. Between 1986 and 1993, I studied at the University of Cincinnati, where I was awarded a M.S. (1988) and a Ph.D. (1993) in Chemical Engineering.

4. I joined Alcon in 1993 as a Senior Scientist in the Drug Delivery Group, a position I held until 2001. As a Senior Scientist in this group, the majority of my work related to the development of novel ophthalmic drug delivery systems.

5. Between 2001 and 2010, I was Manager, and later Associate Director, of the Formulation Development Group at Alcon. In this position, I directed formulation development activities for ophthalmic products, including Alcon's travoprost products TRAVATAN® and TRAVATAN Z®.

6. Between 2010 and March 2013, I was Head of the CMC ("Chemistry, Manufacturing, Controls") Teams Group. In March 2013, I was appointed to my current position as Head of CMC. My responsibilities now include directing the CMC project leaders in the development and execution of the CMC strategy for development and exploratory projects, including in the area of drug formulation.

III. DATA IN THE '299 PATENT SPECIFICATION

7. As the Manager, and later Associate Director, of the Formulation Development Group, I was involved in the research within the Group which led to the inventions claimed in the '299 patent. In particular, I was involved in the development of many of the Example formulations described in the specification of the '299 patent, and as such, I have first-hand knowledge of how certain formulations described in the specification of the '299 patent were made and tested, including the Example formulations discussed herein.

8. In general, when a formulator at Alcon prepares a new formulation, a formulation identification, or "FID," number is assigned. The FID number uniquely identifies a specific combination of ingredients. At times, however, if the combination of ingredients in a particular formulation is adjusted in a way that a new FID number is not deemed necessary, rather than the new formulation being assigned a new FID number, it instead may be assigned a version number, for example FID xxxxxx -1 or FID xxxxxx v. 2.

9. Each batch of a formulation that is made will also be assigned a batch number (and, in some cases, a lot number representing parts of a batch). The batch or lot numbers identify a particular preparation of a particular formulation (identified by the FID number). Batches of a particular formulation are made for a variety of purposes, including to conduct testing on a particular aspect of the formulation—for example, its physical or chemical stability, or its preservative efficacy.

10. I am familiar with Alcon's records relating to this type of formulation and development work. In its usual and ordinary course of business, Alcon issues numbered laboratory notebooks to scientists and technicians, who use the notebooks to record their work relating to the preparation of new formulations. Notebooks may relate to more than one project. A notebook page should generally identify the notebook number, the page number, the title of the experiment and the project number.

11. Other than the formulation and development information, laboratory notebooks may also record other types of testing carried out by other Alcon employees on a particular formulation, such as preservative efficacy testing, chemical stability testing, or physical stability testing. If a formulator wishes to test the preservative efficacy of a formulation, for example, he or she typically sends samples to the microbiology laboratory for testing. Once the testing is

completed, the laboratory provides the formulator with a report. These test results are recorded in the Laboratory Information Management System (LIMS).

12. Alcon maintains laboratory notebooks and laboratory testing reports in the usual and ordinary course of its business, and did so during the discovery and development of the inventions claimed in the '299 patent, including the making and testing of the Examples discussed herein.

A. Examples D – F, L – N, and U – W

13. Examples D, E, F, L, M, N, U, V, and W as set forth in the specification of the '299 patent are each formulations that were created during the discovery and development of the inventions claimed in the '299 patent. The '299 patent correctly identifies the ingredients of each formulation and their concentrations. The '299 patent also correctly identifies (with one minor exception discussed in paragraph 15 below) the particular FID and lot number for each formulation. The particular batches were created by scientists in the Formulation Development Group for the purpose of testing the preservative efficacy of each formulation. I am familiar with the creation by scientists in the Formulation Development Group of the particular batches described in Examples D – F, L – N, and U – W of the '299 patent.

14. Each batch was formulated by scientists in the Formulation Development Group according to standard practices in the field, which are

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