UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.
APOTEX, INC.
Petitioner

v.

ALLERGAN, INC.
Patent Owner

U.S. Patent No. 8,642,556

Case *To be assigned*

Declaration of Harry C. Boghigian

TABLE OF CONTENTS

I, Harry C. Boghigian, hereby declare as follows.

I. Introduction

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

2. I have been retained as an expert witness on behalf of APOTEX CORP. and APOTEX, INC. for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $695 per hour. No part of my compensation is affected by the outcome of this matter or the nature of my opinions in this declaration. I understand that the petition for *inter partes* review involves U.S. Patent No. 8,642,556 ("the '556 patent"), Exhibit APO1001, which resulted from U.S. Application No. 13/967,189 ("the '189 application"), filed on August 14, 2013, naming Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power as inventors. The '556 patent issued on February 4, 2014, from the '189 application. The '556 patent claims the benefit of a provisional application that was filed September 15, 2003. I further understand that, according to the USPTO records, the '556 patent is currently assigned to Allergan, Inc.

3. I understand that the '556 patent is directed generally to the field of ophthalmic drug delivery and formulation, and more specifically to methods and compositions for treating an eye of a human or animal having dry eye disease. APO1001, 1, Abstract. I understand that the claims of the '556 patent are generally

directed to topical ophthalmic emulsions comprising cyclosporin A, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil. APO1001, 11:15:65 to 11:16:10. I understand that the claims of the '556 patent recite a topical ophthalmic emulsion comprising 0.05% by weight cyclosporin A and 1.25% by weight castor oil. *Id.* I understand that the claims of the '556 patent recite topical ophthalmic emulsions that are therapeutically effective for treating dry eye disease. *Id.*

II. Summary of opinions

4. I have been asked to assess whether there is any commercial success attributable to the '556 patent. My declaration focuses on the alleged commercial success of RESTASIS®, which I understand Allergan has asserted is a commercial embodiment of claims of the '556 patent. APO1019, 2620:¶2.

5. Briefly, for at least the reasons set forth below, it is my opinion that the marketplace performance of RESTASIS® does not evince commercial success of the '556 patent's claims:

- RESTASIS®'s world-wide sales revenue, of which its U.S. sales revenue makes up the majority, does not establish commercial success for the '556 patent's claims because it is driven by extrinsic, commercial factors that are unrelated to the '556 patent, such as Allergan's established position in the

market, its effective marketing of RESTASIS®, and the growing market for treating dry eye/KCS.

- Allergan's analysis of RESTASIS®'s sales performance is misleading. Allergan provides evidence of net revenue rather than unit and prescription sales, and it does not attempt to establish market share for global sales. Its analysis of RESTASIS®'s U.S. market share is overstated because Allergan's definition of the relevant market is unduly narrow. Allergan stated: "As there is no other FDA-approved therapeutic treatment for dry eye available on the US market, Restasis® owns 100% of the market share." And even if Allergan's definition of the market was not flawed, a blocking patent prevented meaningful competition. Further, Allergan's analysis ignores the existence of four unexpired U.S. patents that also encompass RESTASIS®. Allergan also failed to establish a nexus with any alleged novel features of the '556 patent's claims that account for RESTASIS®'s sales.

III. My Background and Qualifications

6. In formulating my opinions, I have relied upon my training, knowledge, and experience in the area of product commercialization and market analysis as it relates to intellectual property matters.

7. I am a pharmaceutical executive with more than 40 years' experience in the commercialization and marketing of prescription pharmaceutical products.

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