UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

ALCON RESEARCH LIMITED
Patent Owner

Patent No. 8,268,299

Inter Partes Review Case No. IPR2017-01053

SECOND DECLARATION OF DR. YVONNE M. BUYS, M.D.

Exhibit 1092

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I, Yvonne Buys, do declare as follows:

I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Argentum Pharmaceuticals LLC for a *inter partes* review (IPR) for U.S. Patent No. 8,268,299 ("the '299 patent"). I am being compensated for my time by the hour in preparing this declaration, but my compensation is not tied to the outcome of this matter. I understand that this, my second declaration, will accompany a reply filing in the *inter partes* review proceeding involving the above-mentioned U.S. Patent.

3. In formulating my opinions expressed in this declaration, the documents I considered include Alcon's Patent Owner Response (Paper 22; "POR"), Dr. Parrish's Declaration (ALCON2027) and the documents cited therein, as well as the other documents I cite in this declaration. I also rely on my background knowledge, education, and expertise in this field generally, which I have described previously. *See* EX1021, ¶¶ 3-9; EX1023.

II. TRAVATAN Z DID NOT SATISFY ANY LONG-FELT BUT UNMET NEED

4. Alcon argues that TRAVATAN Z "has met a long-felt need for a highly effective antiglaucoma medication that is free of BAK." POR, pp. 56-58. In support of its arguments, Alcon relies exclusively on the Declaration of Richard

K. Parrish, II, PhD (EX2027). Alcon and Dr. Parrish make various misstatements and/or mischaracterize the references they rely on, and I wish to address those issues in this declaration. I will note, however, that if this declaration fails to address something argued by Alcon or Dr. Parrish, that should not be taken as an admission that I agree with any such arguments raised by Alcon and its experts. Instead, I am simply pointing out in this declaration the arguments and statements made by Alcon and Dr. Parrish that I believe to be the most in need of correction.

A. Alcon Misidentifies The Alleged "Need," To The Extent It Even Existed

5. Alcon argues that "there has been a long-felt need for a highly effective BAK-free antiglaucoma drug that can be provided once per day and that would be less likely to give rise to OSD over an extended period of use." POR, pp. 57-58. Likewise, Dr. Parrish claims that "as of 2006, there was a long-felt need among those treating glaucoma for a highly-effective, BAK-free antiglaucoma drug that would not lead to an increased risk of the exacerbation of OSD symptoms with chronic use." ALCON2027, ¶ 26. However, to the extent that there was a need at all, Alcon mischaracterizes what that need was. First of all, it is not clear why Alcon and Dr. Parrish focus only on glaucoma treatments, since many of the claims of the '299 patent do not seem to be so limited (*e.g.*, claim 1). Alcon suggests that this is appropriate because "glaucoma is one of only two conditions that requires chronic, daily dosing with an ophthalmic composition." POR, 57.

While glaucoma and dry eye may be the most common ocular conditions that require chronic drops, there are many other conditions that may also require chronic daily topical steroids, such as patients who have had corneal transplants, cases of interstitial keratits (herpetic infection of the cornea), and cases of chronic uveitis. Thus, claim 1 does not suggest a pure focus only on glaucoma.

6. The medical problem focused on by Alcon and Dr. Parrish traces back to patients with primary open-angle glaucoma ("POAG") who require intraocular pressure ("IOP") lowering as a result. *Id*., ¶ 17. Alcon and Dr. Parrish then identify ocular surface disease ("OSD") as a potential problem in such patients. *Id*., ¶¶ 24-25. Even if one is limited to just focusing on this medical issue, while those propositions may be true, the weakness with Alcon's and Dr. Parrish's argument is that they then jump straight to the conclusion that these patients need a "highly effective, BAK-free antiglaucoma drug" that will not exacerbate OSD. *Id*., ¶ 26.

7. The problem with this analysis is that Alcon and Dr. Parrish provide no basis or explanation for why this alleged need was focused solely on an antiglaucoma "drug." To the contrary, by 2006 there were other treatment options for patients with primary open-angle glaucoma who exhibited elevated IOP, either with or without OSD symptoms. Thus, to the extent there was a "need" in 2006 at all, it would be more correctly characterized as a need for an antiglaucoma

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