UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

CIPLA LTD.
Patent Owner

Patent No. 8,168,620
Issue Date: May 1, 2012
Title: COMBINATION OF AZELASTINE AND STEROIDS

Inter Partes Review No.: IPR2017-00803

SECOND DECLARATION OF DR. MAUREEN D. DONOVAN, Ph.D.

Exhibit 1165

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I, Maureen Donovan, 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. 8,168,620 (Ex. 1001). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $400 per hour for any consulting and $600 per hour for any deposition appearances. I understand that my declaration accompanies a petition for *inter partes* review involving the above-mentioned U.S. Patent.

II. The Basis For My Opinion

3. In formulating my opinion, the documents I considered include Patent Owner's Response (Paper 21; "POR"), Dr. Smyth's Second Declaration (CIP2150), his deposition transcript (Ex. 1143), Dr. D'Addio's Second Declaration (CIP2148) and his deposition transcript (Ex. 1141), Dr. Herpin's Declaration (CIP2029), the documents cited in each of these, as well as other documents provided by Cipla and submitted as part of the Petitioner's Reply.

4. I understand that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to

a person of ordinary skill in the art (POSA) in view of the prior art, and in light of the general knowledge in the art. I also understand that when a POSA would have reached the claimed invention through routine experimentation, the invention may be deemed obvious. I understand that a finding of obviousness for a specific range or ratio in a patent can be overcome if the claimed range or ratio is proven to be critical to the performance or use of the claimed invention.

5. I also understand that obviousness can be established by combining or modifying the teachings of the prior art to achieve the claimed invention. It is also my understanding that where there is a reason to modify or combine the prior art to achieve the claimed invention, there must also be a reasonable expectation of success in so doing. I understand that the reason to combine prior art references can come from a variety of sources, not just the prior art itself or the specific problem the patentee was trying to solve. And I understand that the references themselves need not provide a specific hint or suggestion of the alteration needed to arrive at the claimed invention; the analysis may include recourse to logic, judgment, and common sense available to a person of ordinary skill that does not necessarily require explication in any reference.

6. I understand that when considering the obviousness of an invention, one should also consider whether there are any secondary considerations that support the

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