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

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

Exhibit 1004

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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.

I. My Background And Qualifications

3. My area of expertise is in the field of pharmaceuticals and nasal formulations. At University of Iowa's College of Pharmacy, I am presently a Professor in the Department of Pharmaceutical Sciences and Experimental Therapeutics within the Division of Pharmaceutics and Translational Therapeutics. I am also the Associate Dean for Undergraduate Education.

4. My research areas include the development and evaluation of novel drug delivery systems for mucosal drug delivery especially via the nasal,

gastrointestinal and vaginal epithelia. I also study the mechanisms of drug absorption and disposition.

5. I obtained a Bachelor of Science in Pharmacy from University of Minnesota in 1983 and a Ph.D. in Pharmaceutics from the University of Michigan in 1989.

6. My *curriculum vitae* is attached as Ex. 1052 to this document.

7. In view of my experiences and expertise outlined above and provided in my *curriculum vitae*, I am an expert in the field of pharmaceuticals and nasal formulations.

II. The Basis For My Opinion

8. In formulating my opinion, I considered the following documents:

Ex. #	Exhibit Name
1001	U.S. Patent No. 8,168,620 ("'620 patent")
1002	Prosecution History of U.S. Patent No. 8,168,620
1006	UK Patent Application GB 0213739.6
1007	U.S. Patent No. 5,164,194 ("Hettche")
1008	Astelin® Label (rev. 2000)
1009	U.S. Patent No. 4,335,121 ("Phillipps")
1010	Flonase® Label (rev. 1998)
1011	European Patent Application No. 0780127 ("Cramer")
1012	PCT Publication No. WO 98/48839 to Segal ("Segal")
1013	British Pharmaceutical Codex (1973)

1014	U.S. Patent Publication No. 20040136918 ("Garrett")
1027	Ansel, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, ch. 7 (6th ed. 1995)
1033	Wade & Weller, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (1994)
1046	IMITREX Prescribing Information (2013)
1048	Rabago, David, et al., "Efficacy of daily hypertonic saline nasal irrigation among patients with sinusitis: A randomized controlled trial," The Journal of Family Practice, Vol. 51, No. 12, 1049-1055 (2002)
1049	Budavari, S., et al. (Ed), "Edetate Disodium," The Merck Index, Eleventh Edition, 550 (1989)
1054	"Avicel® RC-591 Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF, BP," FMC Corporation (1994)

9. 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.

10. 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

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