

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC,
Petitioner

v.

CIPLA LTD.,
Patent Owner

Case No. IPR2020-00369
U.S. Patent No. 8,168,620

DECLARATION OF MAUREEN D. DONOVAN, PH.D.

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I, Maureen D. Donovan, Ph.D., do hereby declare:

1. I am making this Declaration at the request of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (“GSK”) in the matter of *Inter Partes* Review (“IPR”) of U.S. Patent No. 8,168,620 (“’620 Patent”). I understand that the ’620 Patent is owned by Cipla Ltd. (“Patent Owner”) and licensed to Mylan Pharmaceuticals, which acquired Meda Pharmaceuticals.

2. I am being compensated for my work on this matter at my standard consulting rate, which is \$600 per hour for time spent providing testimony, with an eight-hour minimum per day of testimony, and \$400 per hour for time spent on other tasks, such as analyzing documents and drafting declarations. My compensation in no way depends on the outcome of this proceeding or the content of my testimony, and my opinions are based on my own views of the patented technology and the prior art.

I. QUALIFICATIONS AND EXPERIENCE

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.

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 the University of Minnesota in 1983 and a Ph.D. in Pharmaceutics from the University of Michigan in 1989.

6. I have previously provided expert opinions about the '620 *Patent* in a patent infringement litigation and a prior IPR proceeding at the U.S. Patent and Trademark Office ("USPTO"). I understand that these matters are captioned and were resolved as follows: (1) *Meda Pharmaceuticals, Inc. v. Apotex Inc.*, No. 14-cv-01453 (D. Del.) (dismissed by stipulation on May 18, 2017) ("the Apotex litigation"); and (2) *Argentum Pharmaceuticals LLC v. Cipla Ltd.*, IPR2017-00807 (PTAB) (terminated by joint motion on May 21, 2018) ("the Argentum IPR").

7. My curriculum vitae is provided as Appendix A to this Declaration.

8. 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. MATERIALS CONSIDERED

9. I have considered the following documents in preparing this Declaration:

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