UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), INC.
Petitioner

v.

GILEAD PHARMASSET LLC
Patent Owner

Case No. IPR2018-00211
U.S. Patent No. 9,393,256

DECLARATION OF JOSEPH M. FORTUNAK, Ph.D.

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I, Joseph M. Fortunak, declare as follows:

I. QUALIFICATIONS

1. My name is Joseph M. Fortunak. I am a Professor of Chemistry and Pharmaceutical Sciences at Howard University, in Washington, D.C., where I regularly teach courses in Organic Chemistry to undergraduate students. I also teach courses in drug discovery, drug development, pharmaceutical chemistry, pharmaceutical sciences, and green chemistry/chemical synthesis to PharmD and PhD students in Chemistry and Pharmacy.

2. I received my Bachelor of Science in Chemistry from Purdue University in 1976, and my Doctorate in Philosophy in Organic Chemistry from the University of Wisconsin-Madison in 1981. After earning my Ph.D., I was a postdoctoral fellow and a research assistant professor at Cambridge University in the United Kingdom from 1981-1983.

3. My career has spanned both the industrial and academic sectors, including senior managerial and academic appointments.

4. From 1983-1993, I worked at SmithKline Beecham Pharmaceutical Corp., and served as Associate Senior Research Investigator, Senior Research Investigator and Assistant Director. During that time, I was primarily responsible for inventing processes to synthesize active pharmaceutical ingredients ("APIs") for investigational new drugs, including the drugs halofantrine, ropinerole,

topotecan and eprosartan, which the U.S. Food and Drug Administration ("FDA") has approved.

5. From 1993-2000, I worked at DuPont Pharmaceutical Company ("DuPont"), and served as Associate Director, Director, Senior Director and Executive Director. During my tenure at DuPont, among other responsibilities, I led the API development team for the major anti-HIV drug efavirenz, which is an inhibitor of HIV-1 reverse transcriptase. I was also responsible for building a pre-formulations group of experts in organic, solid-state chemistry (i.e. crystalline forms, polymorphs, solvates, hydrates and amorphous forms), and for managing the interface(s) between the API, Formulations, and Analytical groups at DuPont.

6. From 1993-1999 I also served on the Scientific Advisory Board for NaPro Biotherapeutics in Boulder, Colorado, working on a commercial semi-synthesis of the anti-cancer drug paclitaxcel from renewable biomass.

7. From 2000-2004, I worked at Abbott Laboratories as the Head of Global Chemical Development. In that position I was responsible for managing chemistry, engineering, and analytical development for all of Abbott's new drug candidates. During that time, I built a Process Engineering Department with expertise in separation sciences, solids engineering and process modeling. I also was responsible for process validation for four New Drug Applications, including XIENCE™ V drug-device combination (a coronary stent), and emtricitabine, an

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