UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AREGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Patent No. 8,629,111

DECLARATION OF DILEEP BHAGWAT, PH.D.

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I, Dileep Bhagwat, declare as follows:

I. QUALIFICATIONS

1. My name is Dileep Bhagwat. Since 2013 I have worked as a Sr. Pharmaceutical Consultant and CEO of WPDC, LLC which focuses on consulting on Pharmaceutical (Formulation) Development, Quality, Clinical and global Regulatory filings. Over these past four years, I have personally consulted for U.S., Swiss, European, Japanese, and Israeli companies. I spent over 5 months in Basel, Switzerland working on a consulting project for a large Swiss company.

2. I received a B.S. (Pharmacy) degree from Bombay University, India; a M.S. and Ph.D. (Industrial Pharmacy) degrees from St. John's University New York where I was inducted into the Rho Chi Pharmaceutical Honor Society. I also have a management (MBA) degree in International Business from Pace University, New York.

3. I have worked in the Pharmaceutical Industry for over 35 years (of which 25 years were in management positions) in Pharmaceutical Research and Development, Quality, Manufacturing, Regulatory Affairs. I have worked on many dosage forms, for example Solid/liquid oral (Immediate released/controlled release), sub-lingual, intra-nasal, Topicals (patches/creams/lotions/gels/ emulsions), injectables, Metered Dose Inhalers and in multiple therapeutic areas (e.g. Oncology, Pain, Dermatology, GI, CNS, cardiovascular).

4. I am an inventor on 16 issued U.S. patents plus many international patents. I have made many poster and podium presentations at various pharmaceutical and medical conferences including at the American Association of Pharmaceutical Scientists (AAPS), American Pain Society (APS), European Hematology Association, American Society of Hematology (ASH), Controlled Release Society.

5. From 2004 to 2012 I worked at EpiCept Corporation (as part of the management team reporting to the CEO) as Sr. Vice President, Pharmaceutical Development. I was responsible for all aspects of drug product development (Phase I – III) and GMP manufacturing/commercialization/supply chain of pain and oncology compounds in the EpiCept pipeline. I was responsible for QA and global Regulatory CMC submissions for NDA, NDS and MAA.

6. From 1999 to 2004 I worked at Bradley Pharmaceuticals as Chief Scientific Officer reporting to the CEO and responsible for all scientific activities at the company. I was responsible for Product development, Operations Dept. (manufacturing and supply chain), setting up and managing a Clinical program, Regulatory and Quality Assurance and compliance.

7. From 1994 to 1999 I worked at TIMERx Technologies as Vice President, Pharmaceutical R & D, reporting to the President. I organized and modernized the R & D efforts of PENWEST's emerging Oral Controlled Release

business. When Penwest Pharmaceuticals was created by merging the TIMERx and Mendell (excipient) businesses, I served as Vice President, Scientific Development and Regulatory Affairs leading the development and licensing of Penwest's oral controlled release technology. From 1979 to 1994 I worked at Purdue Frederick Research Center in various capacities in Pharmaceutical R & D leading to Assistant Director in the Pharmaceutical Development Division. Prior to that I worked for Hoechst Pharmaceutical, India in manufacturing.

8. A summary of my education, experience, awards and honors, patents is provided in my CV, a copy of which is submitted separately. Ex. 1003.

II. SCOPE OF WORK

9. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 8,629,111 ("the '111 patent," Ex. 1001). I have been retained by the Petitioner as a technical expert to provide analysis and opinions regarding the '111 patent. I have reviewed the '111 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office. Ex. 1004. I have also reviewed and considered various other documents in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XII.

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