Declaration of Dr. S. Jamal Mustafa Regarding U.S. Patent No. 6,645,513

#### UNITED STATES PATENT AND TRADEMARK OFFICE

#### **BEFORE THE PATENT TRIAL AND APPEAL BOARD**

#### PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,645,513

#### **DECLARATION OF S. JAMAL MUSTAFA, Ph.D.**

DOCKET

I, S. Jamal Mustafa, Ph.D., declare as follows:

1. The opinions set forth below are based on my over 42 years of experience as an expert in biochemistry and pharmacology and on the review of materials discussed herein.

#### I. BACKGROUND AND QUALIFICATIONS

2. My *curriculum vitae* ("CV") (a copy of which is attached) highlights my education, experience, and qualifications as an expert in biochemistry and pharmacology. Some of the information relevant to this case is summarized below.

3. I received a Bachelor of Science (B.S.) degree in Chemistry from Lucknow University in 1962, a Master of Science (M.S.) degree in Biochemistry from Lucknow University in 1965, and a Doctorate (Ph.D.) degree in Biochemistry from Lucknow University in 1970.

4. I was an Assistant Dean for Research and Assistant Vice President for Research in the Health Sciences Center at West Virginia University (WVU) in Morgantown, WV, positions I have held since 2005 and 2008 until June 30, 2015, respectively. I am also a Professor in the Department of Physiology & Pharmacology of the WVU School of Medicine, and an Adjunct Professor in the WVU School of Pharmacy, and have been since 2005. Through these programs, I am teaching graduate, medical and pharmacy courses in pharmacology.

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5. From 1980 to 2005, I worked as a Professor or Adjunct Professor in a number of departments of the School of Medicine at East Carolina University, including the Heart Center and the Departments of Pharmacology, Surgery, Medicine, and Physiology. In the past, I have also taught pharmacology courses at the University of South Alabama College of Medicine, and East Carolina University School of Medicine after finishing my post-doctoral training at the University of Virginia, School of Medicine (1971-74).

6. I have participated as Principal Investigator in over thirty grant-based research projects. My present research with the Health Sciences Center involves identifying and studying the role of adenosine receptors in normal and diseased tissues, and studying the roles of second messengers in the regulation of adenosine receptor expression, mostly in heart and lung.

7. Professional honors that I have received while at WVU include the Chancellor's Award for Outstanding Achievement in Research and Scholarly Activities in April 2013, the Robert C. Byrd Professorship in March, 2010, and the Award for Excellence in Research from School of Medicine in April, 2008. As further detailed in my CV, other Professional honors that I have received include: Lifetime Achievement Award in Research and Creative Activities from East Carolina University, June, 2003; First Award for Excellence in Basic Research from East Carolina University School of Medicine, May, 1997.

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8. I have authored or co-authored over 200 articles published in scientific journals on the subject of adenosine, its derivatives, or cellular activity related to adenosine receptors. In addition, I have contributed to at least thirty review articles and/or textbooks, and am on or have been on the Editorial Board of a number of peer-reviewed journals, including *Reactive Oxygen Species* and *American Journal of Pharmacology and Toxicology, Vascular Pharmacology*, as well as many others.

#### II. <u>COMPENSATION, PREVIOUS TESTIMONY, AND</u> <u>RELATIONSHIP TO THE PARTIES</u>

9. I am being compensated at an hourly rate of \$ 350 for the time I spend studying materials and issues associated with this matter and for the time I spend providing testimony. This rate is my standard consulting rate. My compensation is not contingent upon the outcome of this matter.

10. It is my understanding that University of Massachusetts is the assignee of the '513 patent. Prior to this matter, I have not worked for University of Massachusetts, and am aware of no financial interest that I have in the University of Massachusetts.

11.

#### III. MATERIALS CONSIDERED

12. I have reviewed the following materials:

Exhibit No.	Description
1002	U.S. Patent No. 6,645,513 to Dobson <i>et al.</i>
1014	Kathryn M. Neurath et al., AMP-Dependent Protein Kinase Alpha 2 Isoform Promotes Hypoxia-Induced VEGF Expression in Human Glioblastoma, 53 Glia 733, 733–743 (2006).
1015	Geoffrey Burnstock et al., <i>Purinergic Signaling in Healthy and Diseased Skin</i> , 132 J. Invest. Dermatol 526, 526–546 (2012).
1019	R H. Koizumi et al., Adenosine Deaminase in Human Epidermis from Healthy and Psoriatic Subjects, 275 Arch Dermatol Res 310, 310-14 (1983).

#### IV. Adenosine Monophosphate is an Angiogenic Factor

13. Adenosine Monophosphate (AMP) is known to be an angiogenic factor. (Ex. 1014). The property of AMP as an angiogenic factor is inherent and would not have changed over time. In other words, the inherent function of AMP as an angiogenic factor has not changed since 1998.

#### V. Adenosine Metabolizes in the Epidermis

14. It is my understanding that human skin includes many layers,

including an outer, epidermal layer, which covers multiple inner layers (including the dermal layer). (Ex. 1002, col. 1, ll. 25-30). The '513 patent describes the skin as having "a surface layer, known as the epidermis, and a deeper connective tissue layer, known as the dermis." (*Id.*)

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