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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

In the *Inter Partes Review* (IPR) of
U.S. Patent No. 8,822,438

DECLARATION OF DEFOREST MCDUFF, Ph.D.

I, DeForest McDuff, Ph.D., declare as follows:

I. Introduction

A. Qualifications

1. I am a Vice President of Intensity Corporation and an expert in applied business economics, with more than ten years of experience in consulting, finance, and economic research. I provide expert witness testimony and consulting in a variety of areas, including lost profits, reasonable royalties, unjust enrichment, commercial success, finance, statistics, valuation, and business optimization.

2. My expertise and experience span a variety of topics, including intellectual property, competition, antitrust, finance, labor, employment, and class action. My work in intellectual property spans the life sciences (including pharmaceuticals, biotechnology, diagnostics, and medical devices), electronics

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(including consumer electronics, semiconductors, computers, and telecommunications), and has included projects on a diverse range of other industries (such as scuba diving equipment, golf clubs, and contact lenses). I frequently provide expertise and analysis in evaluating commercial success in the pharmaceutical industry.

3. I earned my Ph.D. in economics from Princeton University. At Princeton, I received a National Science Foundation Graduate Research Fellowship for academic research studying economic and statistical properties of housing markets and financial derivatives. I have published research in several peer-reviewed academic journals. I graduated *summa cum laude* with undergraduate degrees in economics and mathematics from the University of Maryland.

4. My curriculum vitae, provided in Attachment A-1, contains more details on my background, experience, publications, and prior expert testimony.

B. Scope of Work

5. Intensity Corporation has been retained by McNeely, Hare & War, LLP on behalf of Amerigen Pharmaceuticals Limited in connection with my work in this matter. Intensity Corporation is being compensated at a rate of \$700 per hour for my work and at lower rates for time spent by others on my team. The

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compensation of Intensity Corporation is not dependent on the substance of my testimony or the outcome of this matter.

6. For this declaration, I was asked to evaluate aspects of commercial success, from an economic perspective, as it pertains to Zytiga (abiraterone acetate) and U.S. Patent No. 8,822,438. This declaration is a statement of my opinions in this matter and the basis and reasons for those opinions. In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed. I have also reviewed, considered, or relied upon documents and other materials, which are cited herein and/or listed in Attachment A-2.

7. This declaration summarizes only my current opinions, which are subject to change depending upon additional information and/or analysis. The entirety of my declaration, including attachments and referenced materials, supplies the basis for my analysis and conclusions. The organizational structure of the declaration is for convenience. To the extent that facts, economic analysis, and other considerations overlap, I generally discuss such issues only once for the sake of brevity. Neither the specific order in which each issue is addressed nor the organization of my declaration or attachments affects the ultimate outcome of my analysis.

II. Background

A. Prostate cancer

8. Prostate cancer occurs in the male prostate, a small gland that produces the seminal fluid that nourishes and transports sperm.¹ Prostate cancer is one of the most common types of cancer in men,² with a one-in-seven lifetime risk

¹ AMERIGEN 1051: Mayo Clinic Website, Prostate cancer, <http://www.mayoclinic.org/diseases-conditions/prostate-cancer/basics/definition/con-20029597?p=1> (accessed 7/24/2015).

² AMERIGEN 1051: Mayo Clinic Website, Prostate cancer, <http://www.mayoclinic.org/diseases-conditions/prostate-cancer/basics/definition/con-20029597?p=1> (accessed 7/24/2015).

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of being diagnosed.³ In recent years, estimates for prostate cancer indicate over 220,000 new cases and more than 27,000 deaths annually in the US alone.⁴

9. Patients diagnosed with prostate cancer may undergo a variety of treatments options, including: (1) active surveillance (*i.e.*, no action taken until disease progresses);⁵ (2) radiation therapy (*i.e.*, using high-powered energy to kill

³ AMERIGEN 1041: Cancer.org (ACS), “What are the key statistics about prostate cancer?”

<http://www.cancer.org/cancer/prostatecancer/detailedguide/prostatecancerkeystatistics> (accessed 8/20/2015).

⁴ AMERIGEN 1041: Cancer.org (ACS), “What are the key statistics about prostate cancer?”

<http://www.cancer.org/cancer/prostatecancer/detailedguide/prostatecancerkeystatistics> (accessed 8/20/2015).

⁵ AMERIGEN 1051: Mayo Clinic Website, Prostate cancer,

<http://www.mayoclinic.org/diseases-conditions/prostate-cancer/basics/definition/con-20029597?p=1> (accessed 7/24/2015).

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