

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. My qualifications are generally described in Section I.A.1 of my initial declaration submitted on December 4, 2015 (“Initial Declaration”).<sup>1</sup> I incorporate those qualifications by reference here. I have also provided an updated curriculum vitae in Attachment A-1 to this declaration, which contains more details on my background, experience, publications, and prior testimony.

**B. Scope of Work**

2. 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 compensation

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<sup>1</sup> AMG 1017: McDuff Declaration, 12/4/2015.

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

3. For this declaration, I was asked to review and discuss the declaration of Dr. Christopher Velluro relating to the alleged commercial success of Zytiga (abiraterone acetate) and U.S. Patent No. 8,822,438 (“the ’438 patent”). 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.

4. 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. Analysis of the Velturo Declaration

### A. Overview

5. Commercial success is a secondary consideration that a patent owner may use to argue that its patent is not obvious based on the alleged commercial success of an invention embodying that patent. I understand that commercial success is relevant to the determination of a patent's obviousness since the law presumes that an idea would have been brought to market sooner in response to market forces had it been obvious to persons skilled in the art.

6. I understand that to show that commercial success demonstrates non-obviousness, one must establish that (1) a product embodying the patented invention is commercially successful (*i.e.*, it achieved marketplace success), and (2) that the marketplace success was driven by the advantages of the claimed invention (*i.e.*, there must be proof of a causal nexus). I further understand that to establish a proper nexus between a claimed invention and the commercial success of a product, a patent owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention, and not a result of economic and commercial factors unrelated to the quality of the patented subject matter. Finally, I understand that if commercial success is due to an element in the prior art, no nexus exists.

7. In my opinion, the Vellturo Declaration has a number of shortcomings and does not establish that Zytiga in combination with prednisone has been a commercial success nor that there is a strong connection or nexus to the alleged innovations of the '438 patent. In addition, none of the opinions or evidence I have reviewed from the Vellturo Declaration has caused me to change my primary opinions from my Initial Declaration. These opinions are discussed in more detail below.

**B. The Vellturo Declaration does not demonstrate that Zytiga is a commercial success**

8. The Vellturo Declaration concludes that Zytiga in combination with prednisone is a commercial success based on: (1) a tabulation of abiraterone sales and calculation of growth without any context for that tabulation and without a comparison of that tabulation to a number of comparable mCRPC drugs in the market, (2) a calculation of market share without defining a relevant market and without including a number of comparable mCRPC drugs with which to compare Zytiga in a market, and (3) a statement that Zytiga is a top 50 drug product without providing other appropriate context.<sup>2</sup> However, Dr. Vellturo's analysis is insufficient to establish the commercial success of the abiraterone-prednisone

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<sup>2</sup> JSN 2044: Vellturo Declaration, 10/10/2016, ¶¶ 41–43.

combination subject to the '438 patent claims. Specifically, it has several shortcomings and fails to show one way or the other whether Zytiga in combination with prednisone has been commercially successful in the context of an obviousness inquiry.

9. In general, a commercial success analysis can provide evidence of a product's absolute success (*i.e.*, its sales and profitability) or its relative success (*i.e.*, its market performance relative to its peers). On both accounts, for the reasons described herein, Dr. Velluro has failed to meet the burden to prove Zytiga's alleged commercial success.

10. First, at its core, the Velluro Declaration fails to provide sufficient context for determining whether abiraterone sales and sales growth are actually substantial relative to the industry or to other potential benchmarks used for evaluating commercial success. The Velluro Declaration also provides no benchmarks for success or comparison of the costs associated with bringing Zytiga to market (see Section II.C. below). Dr. Velluro provides limited comparisons only to two other mCRPC drugs in his calculation of market share, but no comparisons to other mCRPC drugs, such as Xofigo, Provenge, Taxotere, Casodex, and Lupron Depot. Similarly, the Velluro Declaration notes Zytiga's position among top 50 drug products in terms of annual sales, but provides no context for Zytiga's lifetime

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