

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEALS BOARD**

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AMNEAL PHARMACEUTICALS LLC  
Petitioner

v.

HOSPIRA, INC  
Patent Owner

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*Inter Partes* Review No. IPR2016-01580  
Patent 8,648,106

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**DECLARATION OF ALPASLAN YAMAN, PH.D.**

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## I. INTRODUCTION

I, Alpaslan Yaman, Ph.D., declare as follows:

1. I am over 18 years of age. I have personal knowledge of the facts stated in this declaration and could testify competently to them if asked to do so.

2. In this proceeding before the U.S. Patent and Trademark Office (“USPTO”), I have been retained by Amneal Pharmaceuticals LLC (“Amneal” or “Petitioner”) as an independent expert consultant. Although I am receiving compensation at my standard consulting rate for the time that I spend on this proceeding, I have no other interest in its result. I also expect to be reimbursed for reasonable expenses incurred in relation to my consulting. My compensation is independent of the opinions rendered or the outcome of this proceeding.

3. I understand that this proceeding involves U.S. Patent No. 8,648,106 (“the ‘106 patent”), Ex. 1001, issued on February 11, 2014, and that the ‘106 patent issued from U.S. Application No. 13/867,861 (“the ’861 application”), Ex. 1050, filed on November April 22, 2013. The ’861 application was a continuation of U.S. Application No. 13/678,260 (“the ’260 application”), Ex. 1051, which was filed on November 15, 2012, and issued as U.S. Patent No. 8,436,033 (“the ’033 patent”), Ex. 1052. The ’260 application was, in turn, a continuation of U.S. Application No. 13/541,524 (“the ’524 application”), Ex. 1048, which was filed on July 3, 2012, and issued as U.S. Patent No. 8,338,470 (“the ’470 patent”), Ex.

1053. The '524 application, in turn, was a continuation of U.S. Application No. 13/343,672, Ex. 1008, which was filed on January 4, 2012, and issued as U.S. Patent No. 8,242,158 (“the '158 patent”), Ex. 1047. Accordingly, the earliest possible effective filing date of the '106 patent is January 4, 2012.

4. I have been asked by counsel for Amneal to explain the technical subject matter of the '106 patent and its background. I have also been asked to explain whether prior art discloses the compositions claimed in the '106 patent. My opinions are set forth below.

5. Generally, the '106 patent disclosure and claims are directed to a premixed, or ready-to-use pharmaceutical compositions of dexmedetomidine for parenteral administration. Ex. 1001, col. 2, ll. 5 – 10. The specification identifies, as suitable containers for these formulations of the drug, glass vials, ampoules, syringes, and plastic flexible containers, such as polyvinyl chloride (PVC), VisIV™, polypropylene, and CR3 containers. *Id.* at col. 9, ll. 26–33. The specification also exemplifies long term storage results of several premixed pharmaceutical compositions of dexmedetomidine. *Id.* at col. 13, l. 22 – col. 14, l. 58.

6. It is my opinion that a person of ordinary skill in the art (“POSA”) would have had a reason and the know-how to arrive at the subject matter recited in claims 1-9 by combining the disclosure of the 2010 Precedex Label, Ex. 1007, in

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