

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

AMNEAL PHARMACEUTICALS LLC
Petitioner

v.

HOSPIRA, INC
Patent Owner

Inter Partes Review No. IPR2016-01577
Patent 8,242,158

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. 8,242,158 (“the ‘158 patent”), Ex. 1001, issued on August 14, 2012, and that the ‘158 patent issued from U.S. Patent Application Serial No. 13/343,672 (“the ‘672 application”), Ex. 1008, filed on January 4, 2012.

4. I have been asked by counsel for Amneal to explain the technical subject matter of the ‘158 patent and its background. I have also been asked to explain whether prior art discloses the compositions claimed in the ‘158 patent. My opinions are set forth below.

5. Generally, the ‘158 patent disclosure and claims are directed to a

ready to use liquid pharmaceutical composition for parenteral administration to a subject which is comprised of dexmedetomidine (or a pharmaceutically acceptable salt) at a concentration of about 4 µg/mL and is contained within a sealed glass container. Ex. 1001, col. 26, ll. 4-8. The liquid pharmaceutical composition may further comprise sodium chloride at a concentration of between about 0.01 to about 2.0 weight percent and may be formulated as a total volume of 20 mL, 50 mL, or 100 mL. *Id.* at col. 26, ll. 9-18.

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 1-4 by combining the disclosure of the 2010 Precedex label, Ex. 1007, in view of the Palmgren reference, Ex. 1017, with a reasonable expectation of success.

7. Also, it is my opinion that a person of ordinary skill in the art would have had a reason and the know-how to arrive at the subject matter recited in claims 1-4 by considering the disclosure of the 2010 Precedex label, Ex. 1007, in view of Giorgi, Ex. 1015; Eichhorn, Ex. 1016; Palmgren, Ex. 1017; and the Lavoisier Documents, Ex. 1018, with a reasonable expectation of success.

8. Finally, it is my opinion that a person of ordinary skill in the art would have had a reason and the know-how to arrive at the subject matter recited in claims 1-4 by considering U.S. Patent No. 6,716,867 (“the ‘867 patent”), Ex. 1006,

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