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. IPR2016-01579
Patent 8,455,527

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. 8,455,527 ("the '527 patent"), Ex. 1001, issued on June 4, 2013, and that the '527 patent issued from U.S. Patent Application Serial No. 13/678,148 ("the '148 application"), Ex. 1054, filed on November 15, 2012. The '148 application is a continuation of U.S. Application No. 13/541,524, Ex. 1048, now U.S. Patent No. 8,338,470 ("the '470 patent"), Ex. 1053, which is a continuation of U.S. Application No. 13/343,672, Ex. 1008, now U.S. Patent No. 8,242,158 ("the '158 patent"), Ex. 1047, which was filed on January 4, 2012. Accordingly, the earliest possible effective filing date of the '527 patent is January 4, 2012.

4. I have been asked by counsel for Amneal to explain the technical subject matter of the '527 patent and its background. I have also been asked to explain whether prior art discloses the methods claimed in the '527 patent. My opinions are set forth below.

5. Generally, the '527 patent disclosure and claims are directed to premixed pharmaceutical compositions of dexmedetomidine and methods of use of the premixed compositions for sedation. Ex. 1001, col. 2, ll. 3-9, col. 10, ll. 1-25. The specification provides suitable containers including glass vials, ampoules, syringes, and plastic flexible containers, such as polyvinyl chloride (PVC), VisIV™, polypropylene, and CR3 containers. *Id.* at col. 9, ll. 21-29. The specification also provides numerous suitable concentrations for the premixed concentrations, including the claimed concentration range of between about 0.005 to about 50 µg/mL. *Id.* at col. 7, l. 44 – col. 8, l. 19.

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 1-11 and 13 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

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