

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. IPR2016-01579  
Patent 8,455,527

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**DECLARATION OF JAMES GORDON CAIN, MD, MBA, FAAP**

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## I. INTRODUCTION

I, James Gordon Cain, MD, MBA, FAAP, 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. Application 13/678,148 (Ex. 1054, “the ’148 application”) filed on November 15, 2012. The ’148 application was a continuation of U.S. Application No. 13/541,524 (Ex. 1048, “the ’524 application”), which was filed on July 3, 2012, and issued as U.S. Patent No. 8,338,470 (Ex. 1053; “the ’470 patent”). The ’524 application, in turn, was a continuation of the U.S. Application No. 13/343,672 (Ex. 1006), which was filed on January 4, 2012, and issued as U.S. Patent No. 8,242,158 (Ex. 1047; “the ’158 patent”). Accordingly, the earliest

possible effective filing date of the '470 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 compositions claimed in the '527 patent. My opinions are set forth below.

## II. QUALIFICATIONS & BACKGROUND

5. My qualifications and credentials are fully set forth in my *curriculum vitae*, attached hereto as Exhibit A. I am an expert in the fields of clinical anesthesia and sedation, with significant experience with ready-to-use medications. In particular, I am knowledgeable about the use of dexmedetomidine for sedation purposes. For the past 24 years, I have accumulated significant training and experience in these and related fields.

6. In 1987, I received a B.S. in Biology from the University of Scranton. In 1992, I received my M.D. from the School of Medicine at the University of Pittsburgh. From 1992-1993, I attended Yale University as a Primary-Care Internal Medicine intern. Through the Massachusetts General Hospital at Harvard University, I completed my Anesthesiology Residency from 1993-1996 and Critical Care Medicine Fellowship in 1997 as well as my Adult and Pediatric Cardiac Anesthesiology Fellowship from 1995-1996 at the Massachusetts General Hospital and Boston Children's Hospital.

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