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

———

Inter Partes Review No. IPR2016-01578
Patent 8,338,470

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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. 8,338,470 ("the '470 patent"), Ex. 1001, issued on December 25, 2012, and that the '470 patent issued from U.S. Patent Application Serial No. 13/541,524 ("the '524 application"), Ex. 1048, filed on July 3, 2012. The '524 application 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, and claims priority to the '672 application, which was filed on January 4, 2012. 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 '470 patent and its background. I have also been asked to explain whether prior art discloses the compositions claimed in the '470 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.

7.   Subsequent to my postgraduate work, I held the position of Instructor at Harvard University in 1998 and as Assistant and Associate Professor at West

Virginia University from 1998-2005. From 2005 to the present, I have held the position as Visiting Associate Professor at the University of Pittsburgh.

8. In addition to my academic appointments, I am currently the Director of Perioperative Medical Services, Transplant Anesthesiology and Trauma Anesthesiology as well as the Chief Charge Anesthesiologist at the Children's Hospital of Pittsburgh of UPMC. I have been employed as an anesthesiologist and/or intensivist since 1996 in a number of additional roles, as set forth in my CV, Ex. A.

9. Further, from 2000 to the present, I have gained a significant amount of experience in the field of sedation by studying teaching the effect of dexmedetomidine on patients. In particular, I am published in the field of administration of dexmedetomidine and have given a multitude of invited lectures, as enumerated in my CV, Ex. A.

10. I am not an attorney or patent agent and I offer no legal opinions herein. My opinions here are based on my professional experience, scientific expertise, and the materials I have reviewed.

III. INFORMATION CONSIDERED

11. In forming my opinions, I have reviewed the '470 patent, its prosecution history, and other prior art references cited in this declaration. In particular, I have reviewed the exhibits to Amneal's petition listed in Exhibit B

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