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.

TABLE OF CONTENTS

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,

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.