UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.,
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

CASE IPR: Unassigned

DECLARATION OF ROBERT J. VALUCK, Ph.D., R.Ph.

TABLE OF CONTENTS

I, Robert J. Valuck, do hereby declare as follows:

I. Overview

1. I am over the age of eighteen and otherwise competent to make this declaration. This declaration is based on my personal knowledge as an expert in the fields of drug safety, drug abuse prevention, and prescription drug distribution. I understand that this declaration is being submitted together with a petition for a *Inter Partes* Review ("**IPR**") of claims 1-6 of U.S. Patent No. 7,765,107 ("**the '107 patent**," AMN1001.)

2. I have been retained as an expert witness on behalf of Amneal Pharmaceuticals LLC ("**Amneal**") and Par Pharmaceutical, Inc. ("**Par**") for this IPR. I am being compensated for my time in connection with this declaration at my standard consulting rate. I have no personal or financial interest in the outcome of this proceeding.

3. I understand that the '107 patent issued on July 27, 2010, and resulted from U.S. Ser. No. 11/097,985, filed on April 1, 2005. I also understand that the U.S. Patent and Trademark Office ("**USPTO**") records state that the '107 patent is currently assigned to Jazz Pharmaceuticals, Inc. ("**Jazz**").

4. The face page of the '107 patent lists other patent applications. I understand that the '107 patent is related to a patent application which was filed on December 17, 2002.

5. In preparing this declaration, I have reviewed the '107 patent (AMN1001) and its file history (AMN1002). I have also considered each of the documents listed in the table below, in light of general knowledge in the art as of December 17, 2002.

Amneal Exhibit #	***Description***
1003	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides ("**Advisory Committee Transcript and Slides**") (July 13, 2001)
1004	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Division of Neuropharmacological Drug Products Preliminary Clinical Safety Review of NDA 21-196 ("**Preclinical Safety Review**") (July 13, 2001)
1005	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet ("**Briefing Booklet**") (July 13, 2001)
1006	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript ("**Xyrem Video and Transcript**") (July 13, 2001)
1009	Shulman, S., "The Broader Message of Accutane," *Am. J. of Public Health*, 79:1565-1568 (1989)
1010	Lilly et al., U.S. Patent Appl. Pub. No. 2004/0176985 (filed Mar. 18, 2004; published Sep. 9, 2004) ("**Lilly**")
1011	Honigfeld, G., "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47:52-56 (1996)
1012	Burleson, K., "Review of computer applications in institutional pharmacy—1975-1981," *Am. J. Hosp. Pharm.*, 39:53-70 (1982)
1013	Zeldis, J., *et al.*, "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clin. Therapeutics*, 21:319-330 (1999)

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.