

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.

*Inter Partes Review of USPN 7,765,107
Declaration of Robert J. Valuck, Ph.D., R.Ph. (Exhibit 1007)*

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Declaration of Robert J. Valuck, Ph.D., R.Ph. (Exhibit 1007)*

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.

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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.

<i>Amneal Exhibit #</i>	<i>Description</i>
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," <i>Am. J. of Public Health</i> , 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," <i>Psychiatric Services</i> , 47:52-56 (1996)
1012	Burleson, K., "Review of computer applications in institutional pharmacy—1975-1981," <i>Am. J. Hosp. Pharm.</i> , 39:53-70 (1982)
1013	Zeldis, J., et al., "S.T.E.P.S. TM : A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," <i>Clin. Therapeutics</i> , 21:319-330 (1999)

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