

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC., and ROXANE LABORATORIES,  
INC.  
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.  
Patent Owner

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CASE CBM: Unassigned

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

PAR1007

*Covered Business Method Patent Review of USPN 7,668,730  
Declaration of Robert J. Valuck, Ph.D., R.Ph. (Exhibit 1007)*

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*Covered Business Method Patent Review of USPN 7,668,730  
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 (18) 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 Covered Business Methods Patent Review (“**CBM**”) of claims 1-11 of U.S. Patent No. 7,668,730 (“**the ’730 patent,**” PAR1001.)

2. I have been retained as an expert witness on behalf of Par Pharmaceutical, Inc. (“**Par**”) and Roxane Laboratories, Inc. (“**Roxane**”) for this CBM. 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 ’730 patent issued on February 23, 2010, and resulted from U.S. Ser. No. 10/322,348, filed on December 17, 2002. I also understand that the U.S. Patent and Trademark Office (“**USPTO**”) records state that the ’730 patent is currently assigned to Jazz Pharmaceuticals, Inc. (“**Jazz**”).

4. In preparing this declaration, I have reviewed the ’730 patent (PAR1001) and its file history (PAR1002). I have also considered each of the

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documents listed in the table below, in light of general knowledge in the art as of December 17, 2002.

<b><i>Par Exhibit #</i></b>	<b><i>Description</i></b>
<b>1003</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (“ <b>Advisory Committee Transcript and Slides</b> ”) (July 13, 2001)
<b>1004</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Division of Neuropharmacological Drug Products Preliminary Clinical Safety Review of NDA 21-196 (“ <b>Preclinical Safety Review</b> ”) (July 13, 2001)
<b>1005</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet (“ <b>Briefing Booklet</b> ”) (July 13, 2001)
<b>1006</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Video and Transcript (“ <b>Xyrem Video and Transcript</b> ”) (July 13, 2001)
<b>1009</b>	Shulman, S., “The Broader Message of Accutane,” <i>Am. J. of Public Health</i> , 79:1565-1568 (1989)
<b>1010</b>	Spurgeon D., “Advent of Mail-Order Pharmacy Causes Concern Among Some Pharmacists,” <i>Can. Med. Assoc. J.</i> , 152:1485-1486 (1995)
<b>1011</b>	Honigfeld, G., “Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis,” <i>Psychiatric Services</i> , 47:52-56 (1996)
<b>1012</b>	Burleson, K., “Review of computer applications in institutional pharmacy—1975-1981,” <i>Am. J. Hosp. Pharm.</i> , 39:53-70 (1982)

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