

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 IPR2015-00547

Patent 7,765,107

**PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 35 U.S.C. § 313 and 37 C.F.R. § 42.107**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. BACKGROUND	2
A. The Challenge of Restricting Access To A Dangerous But Efficacious Drug.....	4
B. The '107 Patent	6
III. ARGUMENT.....	8
A. The Petition Should Be Denied For Failing To Name All Real Parties-In-Interest	8
1. Legal Standard	9
2. Par's Corporate Structure.....	10
3. Par Inc.'s Parent Companies Control Par Inc.'s Business Operations	12
4. Par Inc.'s Parent Companies Could Have Controlled This IPR And Therefore Are Real Parties In Interest.....	16
(a) Par Holdings, Sky I, Sky II And Par Co. Have The Legal Right To Exercise Control Over This Proceeding	16
(b) At Least Par Holdings And Par Co. Are Exercising Control Over This IPR.....	18
5. The Petition's Filing Date Should Be Vacated In Accordance With Prior Decisions.....	20
6. Correction Of The Petition's Filing Date Would Be Futile And The Petition Should Be Dismissed As Untimely.....	21
B. Ground 1 Should Be Denied Because The ACA Is Not Prior Art.....	22

- 1. Petitioners’ Wayback Machine Evidence Does Not Establish A Publication Date Prior To The ’107 Patent’s Priority Date24
- 2. Petitioners’ Other Arguments Do Not Establish Public Accessibility30
- C. The Instant Petition Should Be Denied Under 35 U.S.C. §§ 314(a) And 325(d) Because It Is Redundant Of An Earlier Filed Petition.....33
- D. The Petition Should Be Denied Because Petitioners Have Failed To Show There Is A Reasonable Likelihood That Any Claim Of The ’107 Patent Is Obvious.....36
 - 1. Petitioners’ Obviousness Arguments Fail Because They Rely On A Declaration Entitled To Little Or No Weight.....36
 - (a) Dr. Valuck’s Opinions Are Unsupported, Verbatim Recitations Of Petitioners’ Conclusory Arguments36
 - (b) Dr. Valuck’s Claim Charts Are Improperly Incorporated By Reference Into The Petition.....37
 - 2. Ground 1: The ACA Materials Do Not Render Obvious The Claimed Inventions38
 - (a) “computerized method;” “exclusive central pharmacy;” and “central database”39
 - (b) “determining with the computer processor current and anticipated patterns of potential prescription abuse . . . from periodic reports generated only by the central database based on prescription request data . . . wherein said request data contain information identifying the patient, [GHB as] the drug prescribed, and credentials of the medical doctor”42
 - 3. Ground 2: TAS In View Of Honigfeld, Elsayed, And Lilly Do Not Render Obvious The Claimed Inventions43

- (a) Petitioners Have Not Provided A Motivation To Combine TAS, Honigfeld, Elsayed, And Lilly44
- (b) The Cited References Fail To Disclose, Teach, Or Suggest Key Elements Of The Claimed Inventions46
 - i. “central database” and “exclusive central pharmacy”47
 - ii. “analyz[ing] for potential abuse situations”48
- (c) Petitioners Have Failed To Provide Any Reason Or Motivation For Their Proposed Modifications To The Prior Art49
- 4. Long-Felt Need Supports The Nonobviousness Of The Claimed Inventions49
- IV. CONCLUSION.....50

I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107(a), Patent Owner Jazz Pharmaceuticals, Inc. (“Jazz”) submits this Preliminary Response to Amneal Pharmaceuticals, LLC’s (“Amneal”) and Par Pharmaceutical, Inc.’s (“Par Inc.”) (together, “Petitioners”) Petition for *Inter Partes* Review (the “Petition”) of U.S. Patent No. 7,765,107 (the “’107 patent”).

Petitioners’ request for *inter partes* review (“IPR”) is both procedurally defective and substantively meritless. Petitioners previously requested covered business method (“CBM”) review of the ’107 patent and other patents in the same family. Those CBM requests were denied and Petitioners filed the present petition to take a second bite at the post-grant review apple. But Ground 1 is based on the same art and arguments as the CBM requests, and Petitioners cannot deny that they were fully aware of all art asserted in Ground 2 at the time they filed the CBM petitions. The Board should exercise its discretion under 35 U.S.C. §§ 314(a) and 325(d) and deny the Petition for this reason alone.

The Petition should also be denied because the Petitioners have failed to name all real parties in interest (“RPI”)—a threshold requirement for IPR. Specifically omitted from the RPI identification are Par Inc.’s parent companies. Each parent company exercises control over Par Inc.’s business operations in general and could have (and do in fact) exercise control over this proceeding.

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.