

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

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,765,107
UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123**

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*Petition for Inter Partes Review
of U.S. Patent No. 7,765,107*

I. Introduction

Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc.’s (collectively “Petitioners”) submit this Petition for *Inter Partes* Review (“Petition”) seeking cancellation of claims 1-6 of U.S. Patent No. 7,765,107 (“the ’107 patent”) (AMN1001) as unpatentable under 35 U.S.C. § 103(a) in view of the prior art.

For example, published materials that were used in an FDA Advisory Committee Meeting (the “Advisory Committee Art” or “ACA”) renders obvious every limitation of the challenged claims more than a year before the ’107 patent’s earliest effective filing date, as set forth in Ground 1. In addition, Ground 2 demonstrates that other drug distribution systems in public use long before the ’107 patent’s earliest effective filing date also would have rendered the challenged claims obvious to a person of ordinary skill in the art (“POSA”).

For the reasons explained below, Petitioners are at least reasonably likely to prevail on the asserted Grounds 1 and/or 2 with respect to the challenged claims. Petitioners request that this Board institute IPR and cancel each of challenged claims 1-6 of the ’107 patent.

II. Grounds for standing (37 C.F.R. § 42.104(a))

Petitioners certify that the ’107 patent is available for IPR and Petitioners are not barred or estopped from requesting IPR of any of the challenged claims.

III. Statement of the precise relief requested and the reasons therefore

The Office should institute IPR under 35 U.S.C. §§ 311-319 and 37 C.F.R.

§§ 42.1-.80 and 42.100-42.123, and cancel claims 1-6—all claims—of the '107 patent as unpatentable under 35 U.S.C. § 103.

IV. Overview

A. Person of ordinary skill in the art (“POSA”)

A POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. A POSA may work as part of a multi-disciplinary team and draw upon not only his or her own skills, but also take advantage of certain specialized skills of others in the team, to solve a given problem. (AMN1007, ¶21.) For example, a POSA would hold a Bachelor’s or Doctor of Pharmacy degree and a license as a registered pharmacist with 3-5 years of relevant work experience, or a computer science undergraduate degree or equivalent work experience and work experience relating to business applications, including familiarity with drug distribution procedures. (*Id.*) Alternatively, a POSA may have a blend of computer science and pharmacy drug distribution knowledge and/or experience. (*Id.*) Such a POSA may have computer science education qualifications and experience relating to computerized drug distribution systems, or pharmacy education qualifications and experience relating to computerized drug distribution systems. (*Id.*) A POSA would have had knowledge of the literature concerning pharmacy practice and prescription drug distribution, such as the prior art presented herein, that was

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