

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACUETICALS, 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. 7,668,730
UNDER 35 U.S.C. § 311–319 and 37 C.F.R. § 42.1–.80, 42.100–.123**

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I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED (37 C.F.R. § 42.22(a))

Par Pharmaceutical, Inc. (“Par”) and Amneal Pharmaceuticals, LLC (“Amneal”) (collectively, “Petitioners”) petition for *Inter Partes* Review (“IPR”) seeking cancellation of claims 1-11 of U.S. Patent No. 7,668,730 (“the ’730 patent”) (PAR1001). According to USPTO records, the ’730 patent is assigned to Jazz Pharmaceuticals, Inc. (“Jazz”).

Published materials used in an FDA Advisory Committee Meeting (the “Advisory Committee Art” or “ACA”) render obvious every limitation of the challenged claims more than a year before the ’730 patent’s earliest effective filing date, as set forth in Ground 1. In addition, and alternatively, other drug distribution systems in public use long before the ’730 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 1-11 of the ’730 patent.

II. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioners certify that the ’730 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 1-11—all claims—of the '730 patent as unpatentable under 35 U.S.C. § 103.

IV. OVERVIEW

A. Person of Ordinary Skill In The Art

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. (PAR1007, ¶20.) 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, for example, including familiarity with drug distribution procedures. Alternatively, a POSA may have a blend of computer science and pharmacy drug distribution knowledge and/or experience. For example, such a POSA may have computer science education qualifications and experience relating to computerized drug distribution systems, or pharmacy

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