

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC and  
PAR PHARMACEUTICAL, INC.  
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.  
Patent Owner

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Case IPR: Unassigned  
Patent 8,731,963

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,731,963  
UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123**

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## **I. Introduction**

Par Pharmaceutical, Inc. (“Par”) and Amneal Pharmaceuticals LLC (“Amneal”) (collectively “Petitioners”) submit this Petition for *Inter Partes* Review (“Petition”) seeking cancellation of claims 1-28 of U.S. Patent No. 8,731,963 (“the ’963 patent”) (PAR1001) as unpatentable under 35 U.S.C. §103(a) in view of the prior art.<sup>1</sup> According to Office records, the ’963 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 at least claims 1–7 & 9–23 more than one year before the ’963 patent’s earliest effective filing date, as set forth in Ground 1. The additional limitations of claims 8 & 24–28 would have also been rendered obvious to a person of ordinary skill in the art (“POSA”) over the ACA in combination with an additional prior art reference more than one year before the ’963 patent’s earliest effective filing date, as discussed below in Ground 2. Accordingly, claims 1–28 of the ’963 patent would

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<sup>1</sup> Petitioners note that the Board recently instituted IPR trials for the following related patents to the ’963 patent on July 28, 2015: 7,668,730 (IPR2015-00554); 7,765,106 (IPR2015-00546); 7,765,107 (IPR2015-00547); 7,895,059 (IPR2015-00548); 8,457,988 (IPR2015-00551); and 8,589,182 (IPR2015-00545).

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have been obvious to a POSA at the time of the invention—irrespective of any alleged objective indicia of nonobviousness.

For the reasons explained below, Petitioners are at least reasonably likely to prevail on the asserted Grounds with respect to the challenged claims. Therefore, Petitioners respectfully request that this Board institute IPR and cancel each of challenged claims 1–28 of the '963 patent.

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

Petitioners certify that the '963 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 1-28—all claims—of the '963 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, ¶21.)

For example, a POSA would hold a Bachelor's or Doctor of Pharmacy degree and

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