

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC. and  
WOCKHARDT BIO AG,

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

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Case IPR2015-00554<sup>1</sup>

Patent 7,668,730

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**PATENT OWNER RESPONSE  
PURSUANT TO 37 C.F.R. § 42.120**

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<sup>1</sup> Case IPR2015-01818 has been joined with this proceeding.

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**I. INTRODUCTION**

Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. (“Petitioners”) filed a petition for *inter partes* review (“Petition” or “Pet.”) seeking cancellation of claims 1-11 of U.S. Patent No. 7,668,730 (the “’730 patent”). Petitioners presented two grounds of unpatentability based on alleged obviousness, but the Board instituted trial on only Ground 1—Petitioners’ argument that claims 1-11 are allegedly obvious over the Advisory Committee Art (Exs. 1003-1006) (the “ACA”). Paper 19 at 46. As explained below, Ground 1 lacks merit.

*First*, Petitioners have failed to meet their burden of proving that the ACA is prior art to the ’730 patent. Specifically, Petitioners have not established that: (1) Exs. 1004-1006 were publicly accessible before the ’730 patent’s critical date; and (2) a POSA would have been sufficiently capable of locating the ACA.

*Second*, even assuming that the ACA is prior art—it is not—Petitioners have failed to meet their burden of showing that: (1) ACA would have disclosed, taught, or suggested certain claim elements; and (2) that a person of ordinary skill in the art (“POSA”) would have been motivated to modify the ACA to arrive at the inventions claimed in the ’730 patent with a reasonable expectation of success.

Accordingly, Jazz respectfully requests that the Board confirm the patentability of claims 1–11 of the ’730 patent.

## II. BACKGROUND

Petitioners are defendants in Hatch-Waxman lawsuits involving the '730 patent; each is seeking to make a generic version of Xyrem<sup>®</sup> which is covered by the '730 patent. Xyrem is the only FDA-approved treatment for cataplexy and excessive daytime sleepiness, both debilitating symptoms of narcolepsy. Ex. 2013 at 1; Ex. 2014 at 1. Xyrem's active ingredient is a sodium salt of gammahydroxybutyric acid ("GHB"), a substance which has been legislatively defined as a "date rape" drug. Ex. 2011 at 1; Ex. 2012 at 3.

As a result, the FDA would never have approved Xyrem without a method of restricting access to the drug that could ensure that its benefits would outweigh the risks to both patients and third parties. In fact, the FDA approved Xyrem under a special regulation, 21 CFR § 314.520 ("Subpart H"), which allows the FDA to approve drugs that are shown to be effective, but that can only be used safely under restricted conditions. Ex. 2013 at 1; Ex. 2014 at 1.

The methods claimed in the '730 patent protect patients and the public from abuse, misuse, and diversion of GHB. *See* Ex. 1001 at 8:36-12:44; *see also id.* at Abstract, 1:41-45.

The independent claims of the '730 patent claim methods of: (i) receiving in a computer processor, at an exclusive central pharmacy, all prescription requests of all patients being prescribed the prescription drug, with the prescription requests

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