Paper No. __
Filed: November 6, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-00554[1]
Patent 7,668,730

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

[1] 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 cancelation 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® 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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