Paper No.__
Filed: June 3, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.

Petitioner,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-01903
Patent 8,731,963

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

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I. INTRODUCTION

Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. ("Petitioners") filed an IPR petition ("Petition" or "Pet.") seeking cancelation of claims 1-28 of U.S. Patent No. 8,731,963 (the "'963 patent"). Petitioners presented two grounds of unpatentability: Ground 1 – claims 1-7 and 9-23 as allegedly obvious over the Advisory Committee Art (Exs. 1003-1006) (the "ACA"); and Ground 2 – claims 8 and 24-28 as allegedly obvious over ACA in view of Korfhage (Ex. 1037). *See* Pet. 9. The Board rejected Ground 1 in its entirety, and partially instituted review on Ground 2 as it relates to claims 24, 26, and 27. *See* Paper 10. As explained below, claims 24, 26, and 27 would not have been obvious.

First, Petitioners have failed to meet their burden of proving that the ACA is prior art to the '963 patent.

Second, even assuming that the ACA is prior art—it is not—Petitioners have failed to meet their burden of showing that the ACA in view of Korfhage would have rendered the challenged claims obvious.

Accordingly, Jazz respectfully requests that the Board confirm the patentability of claims 24, 26, and 27 of the '963 patent.

II. BACKGROUND

Petitioners are defendants in a Hatch-Waxman lawsuit involving the '963 patent; Petitioners are seeking to make generic versions of Xyrem® which are covered by the '963 patent. Xyrem is the only FDA-approved treatment for cataplexy and excessive daytime sleepiness, both debilitating symptoms of narcolepsy. Ex. 2001 at 1; Ex. 2002 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. 2003 at 1; Ex. 2004 at 3.

FDA would not have approved Xyrem without a method of restricting access to the drug that could ensure that its benefits would outweigh the risks to patients and third parties. In fact, FDA approved Xyrem under 21 CFR § 314.520 ("Subpart H"), which allows FDA to approve drugs that are effective, but can only be used safely under restricted conditions. Ex. 2001 at 1; Ex. 2002 at 1.

Claims 24, 26, and 27 of the '963 patent claim computer-implemented systems for treating a narcoleptic patient with a prescription drug that has a potential for misuse, abuse, or diversion, while preventing that misuse, abuse, and diversion by means of various controls. *See* 1001 at 11:7-12:10, 12:23-33; *see also id.* at Abstract, 1:41-45. Each of these claims requires a central computer database to be distributed over multiple computers, and a query that operates over the distributed databases. *See id.* at 11:7-12:10, 12:23-33. Claim 27 additionally

requires using periodic reports, generated from the single computer database, to identify a current pattern or an anticipated pattern of abuse of the prescription drug. *See id.* at 12:23-33.

III. ARGUMENT

A. Petitioners have failed to show, by a preponderance of the evidence, that the ACA (Exs. 1003-1006) is prior art

The parties have briefed and argued Petitioners' failure to show that the ACA qualifies as prior art in related IPRs 2015-00545, -546, -547, -548, -551, and -554. Jazz submits that the Board should apply the decision it reaches in those IPRs here.

B. Claim Construction

In an IPR, claims are to be given their broadest reasonable interpretation in light of the specification in which they appear. *See* 37 C.F.R. § 42.100(b). Claim terms are also to be given their ordinary and customary meaning as would be understood by a POSA, in the context of the entire patent's disclosure, at the time of the invention. *In re Translogic Tech.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Institution Decision, the Board "determine[d] that no claim terms require express construction for purposes of this Decision." Paper 10 at 8. Jazz respectfully submits, however, that the phrase "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database" in dependent claim 27 requires construction.

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