Paper No. __
Filed: May 6, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC
Petitioner,

v.

JAZZ PHARMACEUTICALS IRELAND LTD.
Patent Owner

Case IPR2016-00546
Patent 8,772,306

PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 35 U.S.C. § 313 AND 37 C.F.R. § 42.107

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107(a), Patent Owner Jazz Pharmaceuticals Ireland Ltd. and exclusive licensee Jazz Pharmaceuticals, Inc. (together, "Jazz") submit this Preliminary Response to Amneal Pharmaceuticals LLC's ("Amneal") Petition for *inter partes* review (the "Petition" or "Pet.") of U.S. Patent No. 8,772,306 (the "'306 patent").

Amneal's Petition sets forth substantially the same art and arguments considered and rejected by the Board in *Par Pharmaceutical, Inc. v. Jazz Pharmaceuticals Ireland Ltd. et al.*, IPR2016-00002, Paper 12 (Apr. 12, 2016) (the "Par '306 IPR").[1] Like Par, Amneal "does not account for the prior art's teaching away of the co-administration of GHB and valproate." *Id.* at 12-13. Also like Par, Amneal "has not identified a sufficient basis . . . to conclude that any increased brain levels of endogenous GHB caused by valproate could have been predictably compensated for by a corresponding decrease of at least 5% in the amount of GHB orally administered to patients." *Id.* at 13-14. For at least these reasons, Amneal's Petition should be denied.

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[1] In fact, all of the references asserted in Amneal's Grounds of invalidity were already considered in the Par '306 IPR. *See* IPR2016-00002, PAR1006 (Xyrem Label), PAR1014 (Hechler), PAR1013 (Shinka); PAR1007 (Depakote Label), PAR1008 (Cagnin), PAR1015 (Kaufman).

As explained in more detail below, at the time of the '306 patent's inventions, the prior art would not have provided a person of ordinary skill in the art ("POSA") with any guidance concerning what effect administering valproate would have on GHB in humans. Instead, the prior art considered as a whole would have taught that valproate's effect on both GHB blood levels and GHB pharmacodynamic effects was entirely unpredictable.

Amneal's Petition makes it clear that no prior art disclosed, taught, or suggested reducing the GHB dose in a patient taking valproate. Rather, ***if*** a POSA were concerned with GHB-related side effects occurring in humans concomitantly receiving valproate, then a POSA would have done exactly what the references say to do—stop co-administering the two drugs. The prior art expressly teaches away from the claimed inventions.

Each Ground of Amneal's Petition fails because: (1) Amneal does not show that the prior art would have taught a POSA what the effect of valproate would be on GHB levels or GHB pharmacodynamic effects in human patients; (2) Amneal ignores that the prior art would have taught a POSA away from the claimed inventions; (3) Amneal does not show that a POSA would have been motivated to administer reduced GHB doses even ***if*** the POSA believed that valproate causes negative GHB-related side effects in humans; and (4) Amneal does not show that a POSA would have reasonably expected that the reduced GHB doses would be

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