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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RANBAXY INC.
Petitioner,

v.

JAZZ PHARMACEUTICALS IRELAND LTD.
Patent Owner

Case IPR2016-00024
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 Ranbaxy Inc.'s ("Ranbaxy") Petition for *Inter Partes* Review (the "Petition" or "Pet.") of U.S. Patent No. 8,772,306 (the "'306 patent").

The '306 patent describes and claims novel methods of treating patients with certain sleep disorders using a reduced effective dosage amount of gamma-hydroxybutyrate ("GHB") when GHB is co-administered with valproate.

Ranbaxy's Petition asserts four Grounds of alleged obviousness. Each Ground fails to show a reasonable likelihood that the '306 patent claims would have been obvious. Ranbaxy's obviousness arguments improperly use hindsight to focus on select disclosures from the prior art. Specifically, each Ground in Ranbaxy's Petition is based on at least two unfounded assumptions: (1) the assumption that the prior art would have disclosed to a person of ordinary skill in the art ("POSA") that valproate increases the negative effects of GHB in patients; and (2) the assumption that a POSA would have chosen to titrate down the dose of GHB as a result.

As explained below, at the time of the '306 patent's inventions, the prior art would not have provided a 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.

Additionally, no prior art discloses, teaches, or suggests 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.

Each Ground of Ranbaxy's Petition fails because: (1) Ranbaxy 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) Ranbaxy ignores that the prior art would have taught a POSA away from the claimed inventions; (3) Ranbaxy 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) Ranbaxy does not show that a POSA would have reasonably expected that the reduced GHB doses would be effective for treating the claimed sleep disorders, and do so without resulting side effects. Ranbaxy's additional arguments directed to the '306 patent's claims that also require the administration of aspirin do not add anything to its faulty Petition.

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