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Paper No. 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

JAZZ PHARMACEUTICALS IRELAND LTD. and
JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2016-00002
Patent 8,772,306

Before ERICA A. FRANKLIN, BRIAN P. MURPHY, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Par Pharmaceutical, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet."), requesting institution of an *inter partes* review of claims 1–34 of U.S. Patent No 8,772,306 (Ex. 1001, "the '306 patent"). Jazz Pharmaceuticals Ireland Ltd. and Jazz Pharmaceuticals, Inc. (collectively, "Patent Owner") timely filed a Preliminary Response (Paper 10, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims. We, therefore, decline to institute an *inter partes* review of claims 1–34 of the '306 patent.

A. Related Proceedings

Petitioner has identified a related litigation proceeding in the District of New Jersey: *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, C.A. No. 14-6150 (D.N.J.). Pet. 1. Patent Owner has further identified the following related litigation proceedings involving the '306 patent: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, 2:13-cv-391 (consolidated) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories*, Inc., 2:15-cv-1360 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Wockhardt Bio AG*, 2:15-cv-5619 (D.N.J.); and *Jazz Pharmaceuticals, Inc. v. Lupin Ltd.*, 2:15-cv-6548 (D.N.J.). Paper 8, 1–2. Patent Owner also identified two other cases, *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals*, LLC,

2:15-cv-6562 (D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:15-cv-7580 (D.N.J.), concerning a patent related to the '306 patent. *Id.* at 2.

In addition, Ranbaxy Inc. and Amneal Pharmaceuticals each filed separate petitions for *inter partes* review of the '306 patent. *See* IPR2016-00024; IPR2016-00546.

B. The '306 Patent (Ex. 1001)

The '306 patent issued on July 8, 2014, and claims a priority date as early as March 1, 2013. *See* Ex. 1001, Title Page. It names Mark Eller as the sole inventor. *Id.*

The '306 patent relates generally to methods for improving the safety and efficacy of the administration of gamma-hydroxybutyrate ("GHB") or a salt thereof to a patient. *Id.*, Abstract. More specifically, the '306 patent is concerned with treating patients suffering from certain disorders such as cataplexy or narcolepsy, who are concomitantly receiving treatment with valproate, with a reduced dose of GHB. *Id.* at 1:15–36. The specification states that valproate can increase or prolong the effects of GHB, resulting in unsafe conditions such as excessive daytime sleepiness. *Id.* at 15:19–16:21 . In certain embodiments, the reduced amount of GHB ranges from 1% to 50% of the effective dose normally given to the patient. *Id.* at 1:32–36.

C. Illustrative Claims

Petitioner challenges claims 1–34 of the '306 patent. All of the challenged claims are directed to methods of treating certain sleep disorders by orally administering a reduced dosage of GHB to patients who are concomitantly receiving valproate.

Claims 1, 11, 19, 30, and 33 are independent. Independent claim 1 is illustrative, and reproduced below:

> 1. A method for treating a patient who is suffering from excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus with gamma-hydroxybutyrate (GHB) or a salt thereof, said method comprising:
>
> orally administering to the patient in need of treatment at least 5% decrease in an effective dosage amount of the GHB or salt thereof when the patient is receiving a concomitant administration of valproate, an acid, salt, or mixture thereof.

Independent claims 11, 19, 30, and 33 also require either administering or recommending a reduced dose of GHB to a patient who is taking valproate. Petitioner treats all claims similarly under each ground asserted in the Petition. Therefore, we treat all the claims similarly for purposes of our analysis in this Decision.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the ’306 patent on the following grounds:

References	Basis	Claims challenged
Xyrem 2005 Label,[1] Depakote 2011 Label,[2] Cagnin,[3] Waszkielewicz,[4] and the FDA Guidance[5]	§ 103(a)	1–34
Xyrem 2005 Label, Depakote 2011 Label, Cagnin, Waszkielewicz, Weiss,[6] and the FDA Guidance	§ 103(a)	1–34

II. DISCUSSION

A. Claim Construction

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–

[1] Jazz Pharmaceuticals, Inc., Prescribing Information and Medication Guide for XYREM® (sodium oxybate) (Nov. 18, 2005) (Ex. 1006).
[2] Abbvie, Inc., Prescribing Information and Medication Guide for DEPAKOTE (divalproex sodium) (Oct. 7, 2011) (Ex. 1007).
[3] Cagnin, A. et al., *γ-Hydroxybutyric Acid-Induced Psychosis and Seizures*, 21(2) Epilepsy Behav. 203–05 (2011) (Ex. 1008).
[4] Waszkielewicz, A. et al., *γ-Hydrobutyric Acid (GHB) and Its Chemical Modifications: A Review of the GHBergic System*, 56(1) Pol. J. Pharmacol. 43–49 (2004) (Ex. 1009).
[5] FDA's Center for Drug Evaluation and Research, Guidance for Industry: Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations (Feb. 2012) (Ex. 1011).
[6] Weiss, T. et al., *Gamma-Hydroxybutyrate (GHB) and Topiramate—Clinically Relevant Drug Interaction Suggested by a Case of Coma and Increased Plasma GHB Concentration*, 69(5) Eur. J. Clin. Pharmacol. 1193–94 (2013) (Ex. 1010).

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