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Paper No. 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

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

Case IPR2016-00546
Patent 8,772,306 B1

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, 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

Amneal Pharmaceuticals LLC ("Petitioner") filed a Petition (Paper 1, "Pet."), requesting institution of an *inter partes* review of claims 1–34 of U.S. Patent No 8,772,306 B1 (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

The parties have identified the following related litigation proceedings involving the '306 patent: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, No. 2:13-cv-391 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:15-cv-1360 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Wockhardt Bio AG*, No. 2:15-cv-5619 (D.N.J.); and *Jazz Pharmaceuticals, Inc. v. Lupin Ltd.*, No. 2:15-cv-6548 (D.N.J.). Pet. 58–59; Paper 8. The parties have also identified other cases, including *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, No. 2:15-cv-6562 (D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, No.

2:15-cv-7580 (D.N.J.), concerning a patent related to the '306 patent. Pet. 59; Paper 8.

In addition, the '306 patent was also the subject of petitions for *inter partes* review filed by Ranbaxy Inc. (IPR2016-00024) and Par Pharmaceutical, Inc. (IPR2016-00002). We denied institution in IPR2016-00002. *See Par Pharm., Inc. v. Jazz Pharm. Ireland Ltd.*, Case IPR2016-00002, Decision, Denying Institution of *Inter Partes* Review (Paper 12) (PTAB Apr. 12, 2016). We instituted an *inter partes* review in IPR2016-00024 on limited grounds, but that proceeding was terminated due to settlement before we reached a final decision on the merits. *See Ranbaxy Inc. v. Jazz Pharm., Inc.*, Case IPR2016-00024, Decision, Institution of *Inter Partes* Review (Paper 10) (PTAB Apr. 12, 2016); Order, Termination of the Proceeding (Paper 15) (PTAB May 23, 2016).

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 17:49–62. 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 independent claims similarly under each ground asserted in the Petition.

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 Label,[1] Hechler,[2] Shinka,[3] and Depakote Label,[4]	§ 103(a)	1–34
Xyrem Label, Hechler, Shinka, Cagnin,[5] and Depakote Label	§ 103(a)	1–34
Xyrem Label, Hechler, Shinka, Depakote Label, and Kaufman[6]	§ 103(a)	6, 17, 27
Xyrem Label, Hechler, Shinka, Depakote Label, Cagnin, and Kaufman	§ 103(a)	6, 17, 27

[1] Jazz Pharm., Inc., *NDA 21-196/S-005, FDA Approved Labeling Text Dated 11/18/05* (2005) (Ex. 1005).
[2] Viviane Hechler et al., *γ-Hydroxybutyrate Conversion into GABA Induces Displacement of $GABA_B$ Binding That Is Blocked by Valproate and Ethosuximide*, 281 J. Pharmacology & Experimental Therapeutics 753 (1997) (Ex. 1006).
[3] Toshihiro Shinka et al., *Effect of Valproic Acid on the Urinary Metabolic Profile of a Patient with Succinic Semialdehyde Dehydrogenase Deficiency*, 792 J. Chromatography 99 (2003) (Ex. 1007).
[4] Abbott Labs., *NDA 018723/S-037/S-040/S-043/S-045/S-046, Depakote (Divalproex Sodium) Tablets for Oral Use, FDA Approved Labeling Text Dated October 7, 2011* (2011) (Ex. 1009).
[5] Annachiara Cagnin et al., *γ-Hydroxybutyric Acid-Induced Psychosis and Seizures*, 21 Epilepsy & Behav. 203 (2011) (Ex. 1008).
[6] Elaine E. Kaufman & Thomas Nelson, *An Overview of γ-Hydroxybutyrate Catabolism: The Role of the Cytosolic $NADP^+$-Dependent Oxidoreductase EC 1.1.1.19 and of a Mitochondrial Hydroxyacid-Oxoacid Transhydrogenase in the Initial, Rate-Limiting Step in This Pathway*, 16 Neurochemical Res. 965 (1991) (Ex. 1015).

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