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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RANBAXY INC.,
Petitioner

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

Case No. TBD
Patent 8,772,306

DECLARATION OF DAVID P. ROTELLA, PH.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,772,306

Ranbaxy Ex. 1037

1. I, David P. Rotella, Ph.D., have been retained by Knobbe, Martens, Olson & Bear, LLP, counsel for Ranbaxy Laboratories Limited ("Ranbaxy"). I understand that Ranbaxy is petitioning for *inter partes* review of U.S. Patent No. 8,772,306 ("the '306 patent") (Ex. 1001), and is requesting that the United States Patent and Trademark Office cancel Claims 1-34 of the '306 patent as unpatentable. This declaration addresses the patentability of Claims 1-34 of the '306 patent.

I. BACKGROUND, QUALIFICATIONS, AND COMPENSATION

A. Background and Qualifications

2. I am currently the Margaret and Herman Sokol Professor of Chemistry in the Department of Chemistry and Biochemistry and in the Sokol Institute of Pharmaceutical Life Sciences at Montclair State University. I have been a member of the faculty of this university since 2011.

3. I am currently an adjunct professor in the Department of Pharmaceutical Sciences at the University of Pittsburgh, in the Center for Drug Discovery at Northeastern University, and in the Department of Medicinal Chemistry at the University of Mississippi. I have been a member of the faculty of these departments since 2010, 2010, and 2009, respectively.

4. I am currently a registered pharmacist in the Commonwealth of Pennsylvania.

5. I was formerly a research scientist at multiple pharmaceutical companies during the years 1991-2010, including at Bristol-Myers Squibb PRI, Lexicon Pharmaceuticals, and Wyeth Research/Pfizer. My industry experience focused on drug discovery and development.

6. I received my B.S. Pharm. from the University of Pittsburgh in 1981 and Ph.D. in Medicinal Chemistry from The Ohio State University in 1985. I was a Postdoctoral Scholar in the Department of Chemistry at The Pennsylvania State University from 1985 to 1987.

7. My current research focuses on protein kinase inhibitors for anti-infective and anti-inflammatory applications. Specifically, I work on the discovery of novel agents useful for treatment of parasitic and neurodegenerative diseases, including synthesis of new analogs of a lead structure as potential protein kinase inhibitors and investigation of structure-activity relationships in a compound with HSP90 inhibitor activity.

8. I have authored or co-authored more than 20 abstracts for presentation at professional meetings, 40 peer-reviewed journal articles, and seven book chapters. I have also edited or co-edited five books in the field of Medicinal Chemistry. I have received numerous honors, fellowships and awards, and am an inventor or co-inventor on seven granted patents.

9. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately (Ex. 1024).

B. Compensation

10. I am being compensated at my normal consulting rate of $500 per hour. I have no personal financial interest in any of the entities involved in this litigation, and my compensation does not depend in any way on my testimony, my conclusions or the outcome of my analysis.

II. MATERIALS CONSIDERED

11. Attached is a listing of the documents that I have considered and reviewed in connection with providing this declaration.

III. THE '306 PATENT

12. I have reviewed the '306 patent, including the claims and specification. I have also reviewed the substantive (as opposed to procedural) portions of the prosecution history of the '306 patent. The '306 patent pertains to the treatment of gamma hydroxybutyrate ("GHB") for the treatment of various sleep related disorders. *See* Ex. 1001 at 14 (Col. 1:24-29). According to the '306 patent the "present invention is to improve the safety and efficacy of the administration of GHB of a salt thereof to a patient." *See id.* at Abstract. The '306 patent also states that "[i]t has been discovered that the concomitant administration

of . . . valproate . . . will affect GHB administration." *Id.* Also according to the '306 patent, it was "discovered that valproate increases the effect of GHB on the body, thereby potentially causing an unsafe condition." *Id.*

13. As explained in this declaration, the assertion that the inventors of the '306 patent "discovered that valproate increases the effect of GHB on the body thereby potentially causing an unsafe condition" (*id.*) is incorrect.

14. The '306 patent defines various terms. I address certain terms relevant to my analysis. The '306 patent states: "'Concomitant' and 'concomitantly' as used herein refer to the administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient." *Id.* at 17 (Col. 8:37-41).

15. One skilled in the art would thus understand that the definition of "concomitantly," as recited in the '306 patent, would vary depending on the identity of "the first administered drug," because the "time period during which the effects of the first administered drug are still operative in the patient" would depend on the dose and pharmacokinetics (e.g., metabolism and plasma level) of the first administered drug. *See id.*

16. The '306 patent also states: "The terms 'therapeutically effective amount,' as used herein, refer to an amount of a compound sufficient to treat,

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