UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner

v.

CORCEPT THERAPEUTICS, INC.,
Patent Owner

Case PGR2019-00048
U.S. Patent No. 10,195,214

DECLARATION OF TY CARROLL, M.D.

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I, Ty Carroll, hereby declare and state as follows:

I submit this declaration on behalf of Corcept Therapeutics, Inc. ("Corcept"), the owner of U.S. Patent No. 10,195,214, ("the '214 patent") in connection with the Petition for Post-Grant Review filed by Teva Pharmaceuticals USA, Inc. ("Teva" or "Petitioner").

I. INTRODUCTION

1. In this report, I have been asked to respond to certain opinions in the Declaration of Dr. David J. Greenblatt, M.D. ("Greenblatt Declaration") regarding the alleged invalidity of the '214 patent that was submitted on behalf of Petitioner, as well as to provide my own understanding of the state of the relevant art at the time of the invention claimed in the '214 patent.

2. I am being compensated for my time at my usual rate of $500 per hour. My compensation does not depend in any way on the substance of my testimony or the outcome of this or any other case.

3. I expressly reserve the right to supplement the opinions expressed herein, as well as the bases for my opinions, in response to additional expert declarations submitted by Teva, or any additional discovery or other information provided in this matter.

II. EXPERIENCE AND QUALIFICATIONS

4. I have been a practicing endocrinologist for over 11 years. As a practicing endocrinologist, I spend the vast majority of my time seeing patients, including individuals with Cushing's syndrome. I have treated patients with Cushing's syndrome with mifepristone for at least the last four years.

5. I am also an assistant clinical professor in the Endocrinology Center and Clinics at the Medical College of Wisconsin. I am currently teaching the second year medical student adrenal disease physiology course.

6. I received a B.S. in Biochemistry from the University of Wisconsin in 1998. I then obtained my M.D. from the Medical College of Wisconsin in 2002. Following that, I did my residency in Internal Medicine at the Medical College of Wisconsin and Affiliated Hospitals from 2002-2005. I then completed a fellowship in Endocrinology, Metabolism, and Clinical Nutrition at the Medical College of Wisconsin and Affiliated Hospitals from 2006-2008. I am Board certified by the American Board of Internal Medicine in Endocrinology.

7. During my career I have received numerous honors and awards, including M-Magazine Top Doctors-Endocrinology (2012-2020), "Best Doctors" in America (2013-2018), and the Medical Student Teacher Award (2009).

8. I have served as a reviewer for a number of peer reviewed journals, including European Journal of Endocrinology, Postgraduate Medical Journal,

Clinical Endocrinology, Endocrine Practice, Journal of the American Board of Family Medicine, Endocrinology, and Journal of Clinical Endocrinology and Metabolism.

9. A copy of my curriculum vitae, including a list of publications I have authored, is attached to this declaration as Appendix A.

III. SUMMARY OF OPINIONS

10. I have reviewed the '214 patent, the Greenblatt Declaration, and other materials cited herein. I have been asked by counsel to use March 1, 2017 as the date of invention for the '214 patent claims. It is my opinion that Dr. Greenblatt has failed to establish that any claim of the '214 patent would have been obvious over the cited references and/or general knowledge in the field, at the time of the '214 patent's invention.

11. Specifically, it is my opinion that as of March 2017, a person of ordinary skill in the art ("POSA") would not have had a reasonable expectation of being able to successfully perform the methods claimed in the '214 patent. A POSA would not have reasonably expected that 600 mg of mifepristone daily could be co-administered with a strong CYP3A inhibitor safely and effectively to patients with Cushing's syndrome. Instead, at that time the POSA would have expected that it would not be safe to administer more than 300 mg of daily

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