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 F. PETER GUENGERICH, Ph.D.

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I, F. Peter Guengerich, hereby declare and state as follows:

I submit this declaration on behalf of Corcept Therapeutics, Inc. ("Corcept" or "Patent Owner"), 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. I have been asked to review and respond to certain of the opinions set forth in the Declaration of Dr. David J. Greenblatt, M.D., submitted on behalf of Petitioner.

II. QUALIFICATIONS AND MATERIALS RELIED UPON

2. I am the Tadashi Inagami Professor of Biochemistry in the Department of Biochemistry at the Vanderbilt University School of Medicine.

3. I received a B.S. in Agricultural Science from the University of Illinois, Urbana in 1970. I then obtained my Ph.D. in Biochemistry from Vanderbilt University in 1973 under the guidance of Professor H.P. Broquist. Following that, I was a Postdoctoral Scholar in the laboratory of Professor M.J. Coon in the Department of Biological Chemistry at the University of Michigan Medical School.

4. Subsequent to my postdoctoral work, in 1975 I started as an Assistant Professor of Biochemistry at the Vanderbilt University School of Medicine. In

1980 I was named a tenured Associate Professor of Biochemistry at the Vanderbilt University School of Medicine, and in 1983 I became a (tenured) Professor of Biochemistry at the Vanderbilt University School of Medicine. Since that time, I have held several positions at Vanderbilt University School of Medicine, including: Director, Center in Molecular Toxicology (1981-2011), Harry Pearson Broquist Professor of Biochemistry (2007-2012), Interim Chairman, Department of Biochemistry (2010-2012), Stanford Moore Professor of Biochemistry (2013), and my current position as the Tadashi Inagami Professor of Biochemistry (2013-present).

5. I have decades of experience studying and educating others about drug-drug interactions ("DDI"), including DDIs involving CYP3A inhibitors. Throughout my time at Vanderbilt, I have taught courses on multiple aspects of drug-drug interactions and pharmacokinetics to medical students, graduate students, and post-graduates. I am currently teaching Enzyme Kinetics and Mechanisms. I am also currently teaching Drug Metabolism & Safety, part of a Master's degree class for postgraduate physicians. I teach pharmacokinetics and toxicokinetics in my Biochemical Toxicology class. In addition, I have created an online course for the Pharmacology Department dealing with pharmacokinetics of drug-drug interactions and called Enzyme Kinetics for Drug Discovery & Development.

6. I have extensive experience in the fields of biochemistry and medicinal chemistry with an emphasis on mechanisms of activation and detoxication of drugs, chemical carcinogens, steroids, and toxicants and characterization of enzymes involved in these processes.

7. During my career I have received numerous honors and distinguished lectureships, which are summarized in my curriculum vitae, which is attached as Appendix A.

8. I have published more than 700 original peer-reviewed scientific articles and more than 270 invited reviews and chapters during my career.

9. I currently serve on the Editorial boards for Chemistry and Biodiversity, Critical Reviews in Toxicology, and Drug Metabolism and Disposition. I was previously on the editorial advisory board for Nature Reviews in Drug Discovery. I also served as an Associate Editor of both the journals Molecular Pharmacology and Chemical Research in Toxicology, and since 2013, I have served as Deputy Editor of The Journal of Biological Chemistry.

10. I am a member of the American Chemical Society, including the Divisions of Biological Chemistry, Medicinal Chemistry, and Chemical Toxicology. I served as Chair of the latter Division from 2007-2008 and have held several other offices in the Division of Chemical Toxicology. In 2009, I was named as an American Chemical Society Fellow, in the inaugural class for that

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