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

DECLARATION OF DR. ADRIAN DOBS, M.D.

I, Adrian Dobs, M.D., hereby declare as follows:

1. I am over the age of eighteen (18) and competent to make this declaration.

2. I have been retained as an expert witness on behalf of Teva Pharmaceuticals USA, Inc. for the above-captioned post-grant review (PGR). I am being compensated for my time in connection with this PGR at my standard consulting rate, which is $900 per hour.

3. I understand that this Declaration accompanies a reply in support of a petition for PGR involving U.S. Patent No. 10,195,214 ("the '214 patent") (TEVA1001). I also understand that the '214 patent is currently assigned to Corcept Therapeutics, Inc. The '214 patent states that it is a continuation of provisional application No. 62/465,772, which has a filing date of March 1, 2017. I understand from counsel that that is the earliest date that Corcept can assert as a priority date.

4. In preparing this Declaration, I have reviewed the '214 patent and each of the documents cited in my declaration, in light of general knowledge in the art before March 1, 2017. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the

art ("POSA") (*i.e.*, a person of ordinary skill in the field, as defined further in the following paragraph) prior to March 1, 2017.

5. I understand that a POSA is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. I understand that Dr. Greenblatt has opined that a POSA in the field of the '214 patent

> would have had an M.D., a Pharm. D., and/or a Ph.D. in pharmacology or a related discipline, with at least four years of experience in treating patients with mifepristone and/or CYP3A inhibitors, or, alternatively, studying drug-drug interactions involving CYP3A inhibitors. A POSA would have had knowledge of the scientific literature and skills in those fields before March 15, 2017. A POSA would have also had knowledge of laboratory techniques and strategies used in investigating drug-drug interactions. Also, a POSA may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

TEVA1002, ¶18. I agree with this definition and use it for purposes of my analysis here.

6. I understand that Corcept has argued that a POSA for purposes of the '214 patent would require experience prescribing mifepristone for Cushing's syndrome. My opinions set forth in this declaration would not change if Corcept's definition were used. I note that I am a POSA under both parties' definitions and have been for some time.

7. I am a physician and board-certified endocrinologist with expertise in endocrinology, diabetes and metabolism. I received a B.S. in Nutrition Sciences from Cornell University in 1973. I received my medical degree from Albany Medical College in 1978. Following medical school, I completed a residency program in internal medicine at the Albert Einstein College of Medicine in New York, where I was chief resident from 1981–1982. I thereafter completed a three-year fellowship in endocrinology at the Johns Hopkins University School of Medicine in Baltimore, Maryland. I also hold a Masters of Health Sciences from the Johns Hopkins University School of Hygiene and Public Health.

8. I currently serve as Professor of Medicine and Oncology and Director of the Johns Hopkins Clinical Research Network of the Johns Hopkins Institute for Clinical and Translational Research (JHCRN). I am also the Director of the Johns Hopkins Center for the Reduction of Cancer Disparities of the Johns Hopkins Comprehensive Cancer.

9. I have published extensively on topics that include sex hormones and their relationship to metabolic disorders. Journals publishing my research include the New England Journal of Medicine, Journal of Clinical Endocrinology and Metabolism, JAIDS, and Journal of Andrology. I co-chair the International Registry for Hypogonadal Men.

10. I have been involved with more than fifty clinical trials testing endocrine drugs and hormones, including studies designed to assess potential drug-drug interactions. In addition, I have participated in several FDA-panels and has presented in front of several FDA advisory boards.

11. In my clinical practice, I have cared for patients with Cushing's disease, Cushing's syndrome, and other adrenal disorders. I have prescribed multiple medications to Cushing's syndrome patients, including dexamethasone, mitotane, pasireotide, ketoconazole, mifepristone, and metyrapone.

12. In addition to my educational training and professional and research experiences described above, I have kept abreast of new developments relating to my fields of expertise by reading scientific literature, conferring with colleagues in the field, attending and presenting at scientific conferences, and presenting at invited lectures. Further information regarding my qualifications and credentials is set forth in my curriculum vitae, attached as Exhibit A to this declaration.

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