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: Unassigned
U.S. Patent No. 10,195,214

Title: CONCOMITANT ADMINISTRATION OF GLUCOCORTICOID RECEPTOR MODULATORS AND CYP3A INHIBITORS

DECLARATION OF ATUL KAUSHIK

I, Atul Kaushik, hereby declare as follows:

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

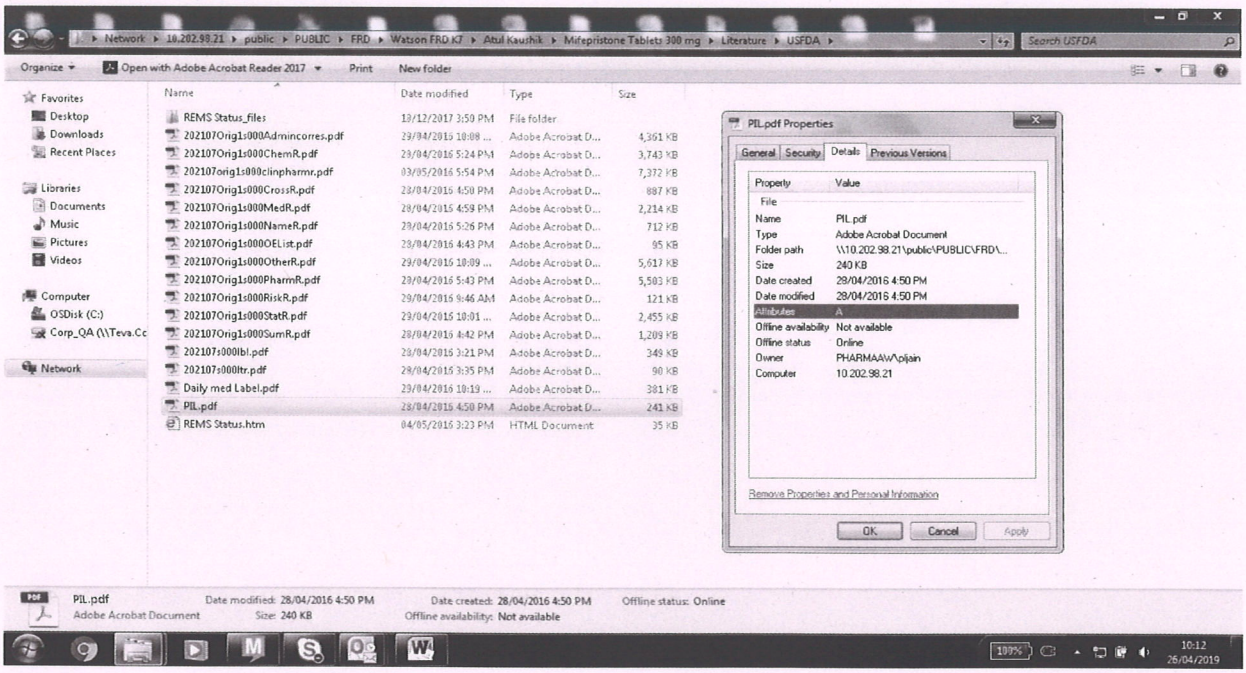
2. I understand that this Declaration accompanies a petition for PGR involving U.S. Patent No. 10,195,214 ("the '214 patent") (TEVA1001).

3. I have personal knowledge of all the facts contained in this declaration.

4. I am Senior Director at Teva Pharmaceuticals USA, Inc. My business address is Plot No. K-7, MIDC, Additional Ambernath (E), Dist.-Thane, India-421506. In this role, I am leading Formulation Research and Development Department. As part of my duties, I routinely review FDA approval packages for branded drugs for which Teva seeks FDA approval to manufacture and distribute a generic equivalent. I, or one of my colleagues at Teva, access these materials by downloading them from the FDA's website.

5. On December 15, 2017, Teva filed Abbreviated New Drug Application No. 211436 seeking to market a generic version of Korlym® (mifepristone) Tablets, 300 mg. Korlym is the subject of Corcept Therapeutic, Inc.'s New Drug Application No. 202107, which was approved by the FDA on February 17, 2012.

6. In April 2016, in connection with Teva's preparation of ANDA No. 211436, my colleague Pritesh Jain downloaded all the materials in the Drug Approval Package for Korlym from the FDA's website. *See* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107_korlym_toc.cfm. This webpage's "Date created" is listed as July 6, 2012. I know that Mr. Jain downloaded the material in early 2016 because it was part of our preparation of ANDA No. 211436. The documents from the Korlym Drug Approval Package were electronically saved on Teva's internal network in April 2016, as shown in the screenshot below, which I took on April 26, 2019.



7. The file named "202107s000lbl.pdf" is a copy of the original FDA-approved label for Korlym that was downloaded from the FDA website. I confirm that Mr. Jain downloaded "202107s000lbl.pdf" in April 2016 as a part of the preparation for Teva's filing ANDA No. 211436. This document is attached to Teva's petition as Exhibit TEVA1004.

8. The file named "202107orig1s000clinpharmr.pdf" is copy of the Clinical Pharmacology Review for Korlym, Office of Clinical Pharmacology Review NDA 20687 (Addendum, KorlymTM, Mifepristone) (2012) that was downloaded from the FDA website. I confirm that Mr. Jain downloaded "202107orig1s000clinpharmr.pdf" in April 2016 as a part of the preparation for Teva's filing ANDA No. 211436. This document is attached to Teva's petition as Exhibit TEVA1005.

9. The file named "202107s000ltr.pdf" is a copy of FDA's approval letter for Korlym that was downloaded from the FDA website. I confirm that Mr. Jain downloaded "202107s000ltr.pdf" in April 2016 as a part of the preparation for Teva's filing ANDA No. 211436. This document is attached to Teva's petition as Exhibit TEVA1006.

10. I accordingly have personal knowledge that the documents attached to Teva's petition as Exhibits TEVA1004, TEVA1005, and TEVA1006 were publicly available on the FDA's website no later than April 2016.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,

Atul Kaushik
[Senior Director-FRD]

Date: May 7, 2019