UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA, S.A.,
Patent Owner.

Patent No. 8,927,592

DECLARATION OF DR. RAHUL SETH

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I, Rahul Seth, declare as follows:

I. QUALIFICATIONS

1. I am currently an Assistant Professor of Medicine at SUNY Upstate Medical University, and I am a practicing oncologist at Upstate University Hospital in Syracuse, NY. My practice includes treatment of prostate cancer patients as a member of the Upstate Specialty Services Prostate Cancer Program. I have been a member of the faculty of SUNY Upstate Medical University since 2009. I am a physician licensed for independent practice in New York, where I have practiced medicine since 2005. I completed my residency in internal medicine in 2002 at Stony Brook University Hospital, where I further completed a fellowship in hematology and oncology in 2005.

2. I obtained my Bachelor of Science degree in Biology in 1991 from Carnegie Mellon University and my Master of Science degree in Biochemistry and Toxicology in 1995 from Brown University. In 1999, I received my Doctor of Osteopathy degree from the New York College of Osteopathic Medicine. I have been board-certified in oncology since 2006.

3. My research and clinical practice is focused on urological oncology and gastrointestinal cancers. I have extensive experience dating back to 2002 in the administration of taxanes for the treatment of prostate cancer. My practice has included treating over 60 patients with metastatic prostate cancer using active chemotherapy, and such treatment typically includes administering taxane drugs. I have also participated in several clinical drug studies, including Phase III clinical trials involving administration of taxane drugs for the purpose of treating cancers.

4. A summary of my education, experience, awards and honors, publications, and presentations is provided in my CV, a copy of which is submitted separately. Ex. 1003.

II. SCOPE OF WORK

5. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 8,927,592 (hereinafter, "the '592 patent," Ex. 1001). I have been retained as a technical expert to provide analysis and opinions regarding the '592 patent. I have reviewed the '592 patent and relevant sections of its prosecution history in the United States Patent and Trademark Office (Ex. 1004). I have also reviewed and considered various other documents in arriving at my opinions, and I cite to them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XI.

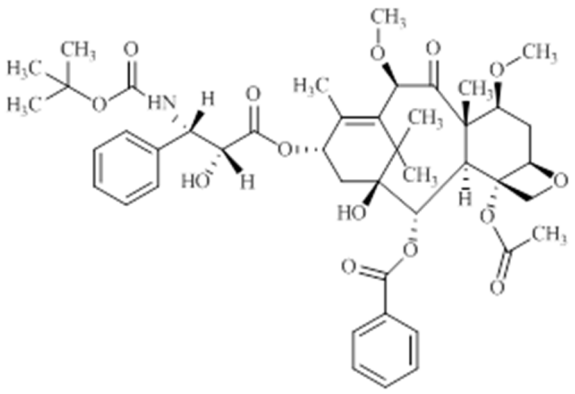
6. I am being compensated at the rate of $670/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE '592 PATENT

7. The '592 patent is entitled "Antitumoral Use of Cabazitaxel." The first page of the patent states that an application for the '592 patent (U.S. Application No. 13/456,720, hereinafter "the '720 application") was filed on April 26, 2012, and is a continuation of International Application No. PCT/IB2010/054866, which was filed on October 27, 2010 and claims priority to seven different U.S. Provisional Patent Applications, the earliest of which dates to October 29, 2009. I have also been advised that claims 7, 8, and 9 of the '592

patent may not be entitled to a priority date earlier than June 17, 2010, the filing date of provisional application 61/355,834 ("the '843 application"), as explained in further detail below.

8. The '592 patent is generally directed to methods of treating prostate cancer, such as metastatic castrate- (or hormone-) resistant prostate cancer ("mCRPC"), by administering cabazitaxel (also referred to as XRP6258; *see*, e.g., Ex. 1004 at 02224). For convenience, the structure of cabazitaxel, as disclosed in the specification of the '592 patent, is shown below:



9. Independent claim 1 of the '592 patent recites the following:

> 1. A method for treating a patient with prostate cancer that has progressed during or after treatment with docetaxel, comprising administering to said patient a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with a corticoid.

10. Dependent claim 2 depends from claim 1 and recites that the prostate cancer is an advanced metastatic disease. Dependent claim 3 depends from claim 1 and recites that the cabazitaxel is in the form of an acetone solvate. Claim 4

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