

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED

Petitioner,

v.

AVENTIS PHARMA S.A.

Patent Owner.

Case IPR2016-00712
U.S. Patent No. 8,927,592

DECLARATION OF ALTON OLIVER SARTOR, M.D.

Aventis Exhibit 2001

Mylan vs. Aventis IPR 2016-00712

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I, Alton Oliver Sartor, declare as follows:

I. QUALIFICATIONS

1. I am the same Dr. Sartor who submitted a declaration under 37 C.F.R. § 1.132 during the prosecution of U.S. Patent Application No. 13/457,720, which I understand issued as U.S. Patent No. 8,927,592 (the “592 patent”). Exh. 1004 at 164-222. I will refer to my previous declaration as the “Prosecution Declaration.”

2. I am the Laborde Professor of Cancer Research in the Medicine and Urology Departments of Tulane University School of Medicine. I am also the Medical Director and Associate Director for Clinical Programs of the Tulane Cancer Center.

3. I received my M.D. from Tulane University in 1982. I completed an internship at the University of Pennsylvania before training in internal medicine at Tulane University School of Medicine. I then completed a fellowship at the National Cancer Institute (“NCI”) in Bethesda, Maryland in 1989. From 1989-1990 I was a Senior Staff Fellow at the Laboratory of Cellular Development and Oncology, National Institutes of Dental Research before serving as a Senior Investigator at the NCI until 1993.

4. In 1993 I returned to Louisiana to serve as Associate Professor of Medicine at the Louisiana State University (“LSU”) Medical School in Shreveport, L.A. and then moved to the LSU Health Sciences Center in New Orleans, L.A. in 1998 as

the Patricia Powers Strong Professor of Oncology, Stanley S. Scott Cancer Center Director, and Hematology/Oncology Section Chief. I became the Co-Director of the Louisiana Cancer Research Consortium at its origin in 2002.

5. In 2006 I left LSU and joined the Lank Center for Genitourinary Oncology at the Dana Farber Cancer Research Institute and Harvard Medical School. In 2008 I joined Tulane University. Further information regarding my academic background and work experience can be found in my curriculum vitae, a copy of which is submitted separately in Exhibit 2002.

6. During the course of my career, my interests have focused on treating prostate cancer, particularly in patients who have failed initial therapy. I have published more than 300 scholarly articles, including many on clinical trials of agents to treat prostate cancer. These publications have been cited more than 14,000 times.

7. I have been appointed to numerous scientific committees. I am currently serving as Chairman of the Tulane Cancer Center Strategic Planning Committee; Medical Chair of the Genitourinary Committee of NRG Oncology (the world's largest radiation oncology research group); and served as an FDA Public Workshop Panelist in 2013 on Clinical Trial Design Issues - Drug & Device Development for Localized Prostate Cancer.

8. I have served on the editorial boards of scientific journals such as The Prostate, Urology, and Personalized Medicine in Oncology. I am currently Editor-in-Chief of the Clinical Genitourinary Cancer journal.

9. I continue to treat patients at the Tulane Cancer Center and Urology Multi-Disciplinary Clinic. I see approximately 25-50 patients per week with urologic malignancies. Currently about 1000 patients are under my care, mostly with prostate cancer. From 2005-2016, I have been named one of the “Best Doctors in America” by Best Doctors, Inc.

10. I was a principal investigator (“PI”) or co-PI on numerous prospective international clinical trials evaluating new therapies for patients with advanced prostate cancer, including five pivotal trials that have led to FDA approvals. I was a co-PI on the TROPIC phase III study comparing cabazitaxel plus prednisone to mitoxantrone plus prednisone in patients with metastatic castration-resistant prostate cancer (“mCRPC”) previously treated with a docetaxel-containing treatment, a study sponsored by Sanofi. I understand Sanofi to be a related company to Aventis Pharma S.A. I am currently a co-PI on another phase III clinical trial of cabazitaxel, also sponsored by Sanofi.

11. I have significant experience in the clinical evaluation of cancer treatments, evaluation of novel treatments for patients with prostate cancer that have failed initial therapies, and treatment of patients with advanced prostate

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