UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN LABORATORIES LIMITED
Petitioner,
v.
AVENTIS PHARMA S.A.
Patent Owner.

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

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EXPERT DECLARATION OF MICHAEL E. TATE

Aventis Exhibit 2149
Mylan v. Aventis, IPR2016-00712

I. INTRODUCTION

1. My name is Michael E. Tate. I have been retained as an expert in this case by Aventis Pharma S.A. ("Aventis") and counsel for Aventis. I understand that the commercial success of a product can be used as a secondary consideration in demonstrating the non-obviousness of the underlying patented invention. The following declaration contains my expert testimony regarding certain aspects of secondary considerations relating to the obviousness of the subject matter claimed in U.S. Patent No. 8,927,592 ("the '592 patent").

2. This declaration is based upon information currently known to me. I reserve the right to rely upon any additional information that becomes available to me after the date of this declaration as well as to amend or modify this declaration to reflect such information or if further research or analysis warrants. I also reserve the right to offer rebuttal testimony to any evidence or argument advanced by Mylan Laboratories Limited ("Mylan") regarding issues of commercial success. Attached to this declaration are schedules summarizing and supporting my opinions.

II. PROFESSIONAL AND EDUCATIONAL BACKGROUND

3. I am a Vice President of Charles River Associates ("CRA") in its Chicago office. CRA is an international business consulting firm focusing on, among other things, intellectual property matters in the context of strategy, licensing, valuation and litigation consulting. CRA is a leading provider of expert damage analysis and testimony for complex intellectual property litigation matters.

4. I obtained a Bachelor of Business Administration degree, with a concentration in finance, from the University of Houston in Houston, Texas. Thereafter, I obtained a Master of Science degree in Industrial Administration from Purdue University in West Lafayette, Indiana.

5. I have served as a consultant to a wide variety of business and industrial clients on matters involving financial analysis and modeling for the purpose of interpreting and projecting data and evaluating the economic impact of business decisions, transactions and economic events. I have served as an expert witness or consultant in a wide range of litigation matters, including patent, copyright, trademark and trade secret infringement litigation. My work on patent litigation matters has involved the quantification of economic damages and an evaluation of commercial success. I have also advised clients on strategic and valuation issues relating to intellectual property and license negotiations.

6. My curriculum vitae is attached hereto at Schedule 1.

7. CRA is being compensated on a rate times hours basis for the work my staff and I perform. My current rate is $615 per hour. CRA's compensation does not depend in any way on the outcome of this litigation.

III. INFORMATION RELIED UPON

8. In performing the analysis and developing the opinions reflected in this report, I relied upon certain documents provided to me by counsel for Aventis, along with certain publicly available information. A list of the information I have cited to is attached hereto in Schedule 2.

IV. BACKGROUND

9. I understand from counsel that Mylan has filed a petition for inter partes review alleging that the '592 patent is invalid for obviousness. I further understand that the '592 patent covers cabazitaxel injections sold under the brand name Jevtana®.[1] Jevtana® is approved for the treatment of hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.[2] Jevtana® was launched in the U.S. in July 2010.[3]

[1] Expert Declaration of Dr. Alton Oliver Sartor (Exh. 2176) at ¶ 192-195, 240.
[2] September 2016 Jevtana® Label (Exh. 2150) at 3.
[3] Sanofi-Aventis SEC Form 20-F (2010) (Exh. 2128) at 89/355; FDA News Release, *FDA Approves New Treatment for Advanced Prostate Cancer* (June 17, 2010) (Exh. 2059) at 1.

A. The '592 Patent[4]

10. The '592 patent, titled "Antitumoral Use of Cabazitaxel," issued January 6, 2015. The '592 patent claims methods of treating patients with prostate cancer that has progressed during or after treatment with docetaxel by administering 20-25 mg/m^2 of cabazitaxel in combination with a corticoid.[5]

B. Prostate Cancer Overview

11. Prostate cancer is the second most common cancer among American men, with 1 in 7 men expected to be diagnosed with the disease during their lifetime.[6] Cancerous cells in the prostate gland may form a tumor, and the tumor may spread from the prostate to other areas of the body, such as the bones, the blood, the lymph nodes, or other organs.[7] Prostate cancer that has spread outside of the prostate is described as advanced or metastatic.[8] Some of the symptoms that can be caused by advanced prostate cancer include pain in the hips, back, and other

[4] The discussion in this section is based on the '592 patent and the Expert Declaration of Dr. Sartor.
[5] Exh. 2176 at ¶ 28.
[6] *What is Prostate Cancer?*, Jevtana.com, http://www.jevtana.com/what-is-prostate-cancer (Exh. 2151).
[7] Exh. 2151 at 1.
[8] Exh. 2151 at 1.

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