

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
Patent 8,927,592

EVIDENTIARY DECLARATION OF MR. ROBERT MCSORLEY

MYLAN - EXHIBIT 1094

I, Robert McSorley, declare as follows:

1. I am the same Robert McSorley who previously submitted a declaration (EX1044; “Original Declaration”) in this *Inter Partes Review* (“IPR”) proceeding, filed with the Petitioner’s Reply and Opposition to Contingent Motion to Amend on March 14, 2017. My Original Declaration set forth my credentials, qualifications, and publications. My *curriculum vitae* was included with the Original Declaration as **Attachment 1**. That information all remains the same.

2. I make this Declaration based on my personal knowledge and inspection of Exhibits 1044, 1057, 1060-1079, and 1089-1090.

3. I note that my Original Declaration contained six consecutive paragraphs numbered as follows: 69, 70, 71, 70, 71, 72. For purposes of clarity, these paragraphs may be referred to, respectively, as follows: 69, 70, 71, 70.A, 71.A, 72. I have attached hereto a copy of Confidential Exhibit 1044 in which I have caused to be interlineated the designation “A” to demarcate paragraphs 70.A and 71.A, as discussed above.

4. I have reviewed and am familiar with Exhibit 1057, which is a true and correct copy of the online article of the Encyclopaedia Britannica (last accessed on March 14, 2017) describing the former German chemical concern Hoechst Aktiengesellschaft that eventually underwent a merger to form Aventis. The article is available on the Encyclopaedia Britannica web site. It is accepted practice among

economic and financial experts to rely upon such encyclopedia articles as a reliable source of information.

5. I have reviewed and am familiar with Exhibit 1060, which is a true and correct copy of the Taxotere Label (Package Insert) that is available for download from the “Drugs@FDA” database, which is a database of drug information hosted by the U.S. Food and Drug Administration. The Drugs@FDA database identifies Exhibit 1060 as the Taxotere Label, SUPPL-63, with a date of April 13, 2012. It is accepted practice among economic and financial experts to rely upon FDA records from the FDA website as authentic copies of those public records.

6. I have reviewed and am familiar with Exhibit 1061, which is a true and correct copy of a September 11, 2014 Medscape article relating to the FDA approval of the drug Xtandi. Medscape is a website (www.medscape.com) that provides news and information related to the healthcare field. The article was downloaded from the Medscape website on March 13, 2017. I have relied on such articles from Medscape and similar websites in my own research and practice outside the context of litigation.

7. I have reviewed and am familiar with Exhibit 1062, which is a true and correct copy of a drug information page from chemocare.com relating to the drug mitoxantrone. The article was downloaded from the Chemocare website on March 14, 2017. I have relied on such articles from Chemocare and similar websites in my own

research and practice outside the context of litigation.

8. I have reviewed and am familiar with Exhibit 1063, which is a true and correct copy of a drug information page from chemocare.com (“Chemocare”) relating to the drug estramustine. Chemocare is a website that provides information relating to chemotherapy and other anticancer drugs sold in the healthcare market. The article was downloaded from the Chemocare website on March 14, 2017. I have relied on such articles from Chemocare and similar websites in my own research and practice outside the context of litigation.

9. I have reviewed and am familiar with Exhibit 1064, which is a true and correct copy of a 2000 article from *Drugs & Therapy Perspectives* reproduced on Medscape. The article relates to the drug Ketoconazole. The article was downloaded from the Medscape website on March 14, 2017. I have relied on such articles from Medscape and similar websites in my own research and practice outside the context of litigation.

10. I have reviewed and am familiar with Exhibits 1065, 1068-1072, 1074, and 1079, each of which bear markings from Sanofi or Aventis and each of which bears numbering with the prefix “SA_JEV.” I understand that each of these documents was produced in this proceeding (IPR2016-00712) from the records of the Patent Owner and that the Patent Owner has not challenged the authenticity of these

documents. As Mr. Tate has relied upon a subset of similar documents (e.g., Exhibits 2170-2171) in support of his opinions, it is appropriate for an expert in my field to evaluate Mr. Tate's opinions in the context of the remainder of the available documents, including Exhibits 1065, 1068-1072, 1074, and 1079.

11. I have reviewed and am familiar with Exhibit 1066, which is a true and correct copy of an article on off-label drug use published on the American Cancer Society's website, www.cancer.org. The article was downloaded from www.cancer.org on March 14, 2017. I have relied on information from the American Cancer Society's website in my own research and practice outside the context of litigation as a reliable source of information on cancer.

12. I have reviewed and am familiar with Exhibit 1067, which is a true and correct copy of the National Drug Monograph for cabazitaxel, provided online by the Pharmacy Benefits Management Services of the U.S. Department of Veterans Affairs (www.pbm.va.gov). The monograph is available for download at <http://www.pbm.va.gov/clinicalguidance/drugmonographs/CabazitaxelDrugMonograph.doc> (last accessed March 14, 2017) and bears a date of March 2011. It is accepted practice among economic and financial experts to rely upon government records from the U.S. Department of Veterans Affairs as authentic copies of those public records.

13. I have reviewed and am familiar with Exhibit 1073, which is a true and

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