

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  
Patent No. 8,927,592

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**SECOND EVIDENTIARY DECLARATION OF PATRICK M. MEDLEY**

MYLAN - EXHIBIT 1095  
Mylan Laboratories Limited v. Aventis Pharma S.A.  
IPR2016-00712

AVENTIS EXHIBIT 2262  
Mylan v. Aventis IPR2016-00712

I, Patrick M. Medley, declare as follows:

1. I am the same Patrick M. Medley who previously submitted an evidentiary declaration (EX1038) in this *Inter Partes Review* (“IPR”) proceeding.

2. I provide this Declaration in connection with the above-identified *Inter Partes Review* proceeding that was requested at the United States Patent and Trademark Office by Mylan Laboratories Ltd. under 35 U.S.C. §§ 311-319, 37 C.F.R. § 42. Unless otherwise stated, the facts stated in this Declaration are based on my personal knowledge.

3. Exhibit 1052 is a true and correct copy of Exhibit 1022A in *Coal. For Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136, as downloaded from the PTAB E2E website for that case.

4. I have reviewed the affidavits of Christopher Butler (EX1026 and EX2142) submitted by Mylan and Aventis, respectively in this proceeding. I understand based on these affidavits that the Internet Archive records copies of web files published on the internet, and makes these files available through the Wayback Machine service. EX1026, 1; EX2142, 1. I understand that these files are copied automatically by web crawlers and preserved as they exist at the time of capture. *Id.* I further understand that the time of capture is encoded in the format of the URL for each file stored in the Internet Archive, as follows:

“http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code

in hh:mm:ss]/[Archived URL].” *Id.* I further understand that both HTML and PDF files are archived in the same manner. EX2142, 1; *see also* EX1025, 1.

5. Exhibit 1045 is a true and correct copy of the NCCN Antiemesis Guidelines, downloaded from the Internet Archive at the URL [http://web.archive.org/web/20081001233326/http://www.nccn.org/professionals/physician\\_gls/PDF/antiemesis.pdf](http://web.archive.org/web/20081001233326/http://www.nccn.org/professionals/physician_gls/PDF/antiemesis.pdf). I understand based on the Affidavits of Christopher Butler (EX1026 and EX2142, discussed above in ¶4) that the URL of this file indicates that it was recorded and preserved automatically by the web crawlers of the Internet Archive on October 1, 2008.

6. Exhibit 1053 is a true and correct copy of Michael *et al.*, “Prostate cancer chemotherapy in the era of targeted therapy” (“Michael”), as obtained from the URL <http://www.nature.com/pcan/journal/v12/n1/pdf/pcan200832a.pdf>. The article states on its face that it was published online on June 3, 2008. The online table of contents of *Prostate Cancer and Prostatic Diseases* (<http://www.nature.com/pcan/journal/v12/n1/index.html>) indicates that Michael was published in print in the March 2009 issue (Volume 12, Issue 1), and that it received “advance online publication” on June 3, 2008.

7. Exhibit 1046 is a true and correct copy of Takenaka *et al.*, “Combination chemotherapy with weekly docetaxel and estramustine for hormone refractory prostate cancer in Japanese patients” (“Takenaka”). The article states on

its face that it was published in 2008 in volume 15 of the *International Journal of Urology*. The Wiley Online Library provides copies of articles of the *International Journal of Urology*, and the online table of contents for volume 15, issue 1 indicates that Takenaka was published online on January 1, 2008 (See <http://onlinelibrary.wiley.com/doi/10.1111/iju.2008.15.issue-1/issuetoc>).

8. Exhibit 1047 is a true and correct copy of Trudeau *et al.*, “Docetaxel in Patients with Metastatic Breast Cancer: A Phase II Study of the National Cancer Institute of Canada-Clinical Trials Group” (“Trudeau”). The article states on its face that it was published in 1996 in volume 14, issue 2 of the *Journal of Clinical Oncology*. I have confirmed that the table of contents for volume 14, issue 2 of the *Journal of Clinical Oncology* indicates that Trudeau was published on February 1, 1996.

9. Exhibit 1048 is a true and correct copy of Hudis *et al.*, “Phase II and Pharmacologic Study of Docetaxel as Initial Chemotherapy for Metastatic Breast Cancer” (“Hudis”). The article states on its face that it was published in 1996 in volume 14, issue 1 of the *Journal of Clinical Oncology*. I have confirmed that the table of contents for volume 14, issue 1 of the *Journal of Clinical Oncology* indicates that Hudis was published on January 1, 1996.

10. Exhibit 1049 is a true and correct copy of Doenicke *et al.*, “Premedication with H<sub>1</sub> and H<sub>2</sub> blocking agents reduces the incidence of

postoperative nausea and vomiting” (“Doenicke”). The article states on its face that it was published in 2004 in volume 53, supplement 2 of *Inflammation Research*. I have confirmed that the table of contents for volume 53, supplement 2 of *Inflammation Research* indicates that Doenicke was published in August of 2004.

11. Exhibit 1050 is a true and correct copy of Cabrespine *et al.*, “Randomized phase II study comparing paclitaxel and carboplatin versus mitoxantrone in patients with hormone-refractory prostate cancer” (“Cabrespine”). The article states in its footer that it was published in 2006 in volume 67, issue 2 of *Urology*. I have confirmed that the table of contents for volume 67, issue 2 of *Urology* indicates that Cabrespine was published online on January 25, 2006.

12. Exhibit 1051 is a true and correct copy of Padhani *et al.*, “The RECIST criteria: implications for diagnostic radiologists” (“Padhani”). The article states on its face that it was published in November of 2001 in volume 74 of *The British Institute of Radiology*. I have confirmed that the table of contents for volume 74, issue 887 of *The British Institute of Radiology* indicates that Padhani was published in issue 887 in 2001.

13. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements

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