

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Inter Partes Review No. IPR2016-01332

U.S. Patent No. 8,822,438

DECLARATION OF MARC B. GARNICK, M.D.

1. I, Marc B. Garnick, M.D., am over the age of eighteen (18) and otherwise competent to make this Declaration. I have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. I have been retained by counsel for Mylan Pharmaceuticals Inc. (“Mylan” or “Petitioner”) in connection with the above-captioned *inter partes* review (“IPR”).

3. I am educated and experienced in medicine, including prostate oncology, as detailed in my previous Declaration that was filed with the Petition as Exhibit MYL 1002, and my Curriculum Vitae filed as Exhibit A to MYL 1002. I understand that my declaration will be included in Petitioner’s Exhibit List as MYL Ex. 1083. I have examined Exhibits 1019, 1025, 1028, 1040, and 1041. All of the exhibits are publicly available, or derived from documents that are publicly available.

4. MYL 1025 is a true and correct copy of two chapters of Kasper, D.L. *et al.* (Eds.), *Harrison’s Principles of Internal Medicine* (16th ed. 2005). MYL 1025 comprises the cover page, date of publication, authorship, table of contents, Chapter 81, entitled “Hyperplastic and Malignant Diseases of the Prostate” and Chapter 321, entitled “Disorders of the Adrenal Cortex,” the two chapters cited in my declaration. MYL 1025 comprises excerpts from a publicly available document. The chapters making up MYL 1025, as initially provided, were

complete. The Patent Owner's Objections to Evidence Pursuant to 37 C.F.R. § 42.64(b)(1) do not point to any reason that the chapters making up MYL 1025 were not complete.

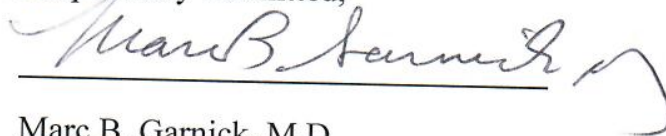
5. MYL 1040 is a true and correct copy of a document entitled *Treatment of Metastatic Castration Resistant Prostate Cancer* accessed and printed on June 28, 2016, by me or under my direction from the webpage of the American Society of Clinical Oncology ("ASCO") at www.cancer.net at the URL or webpage address of: <http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer>. To print this document, I or someone under my direction accessed the ASCO website (www.cancer.net) on June 28, 2016, at the URL or webpage address at <http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer> and clicked on the "print" button on the browser. The resulting document is MYL 1040 and therefore is complete. MYL 1040 is publicly available including from the ASCO website at <http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer>.

6. MYL 1041 is a true and correct copy of a webpage from the American Cancer Society's website at www.cancer.org, which was accessed and printed on

June 28, 2016, by me or under my direction from the webpage of the American Cancer Society (“ACS”) at the URL or webpage address of: <http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics>. To print this document, I or someone under my direction accessed the ACS website (www.cancer.org) on June 28, 2016, at the URL or webpage address at <http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics> and clicked on the “print” button on the browser. The resulting document is MYL 1041 and therefore is complete. MYL 1041 is publicly available including from the ACS website at <http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics>.

February 8, 2017

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Marc B. Garnick", written over a horizontal line.

Marc B. Garnick, M.D.