

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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WOCKHARDT BIO AG,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

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Case IPR: 2016-01582

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

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**DECLARATION OF LESTIN L. KENTON JR.**

***Mail Stop "PATENT BOARD"***

Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

I, Lestin L. Kenton Jr., declare as follows:

1. I am currently employed as an Associate Attorney at Sterne, Kessler, Goldstein & Fox P.L.L.C. I am more than twenty-one years of age, and I make this declaration based on my personal knowledge, experience, and belief.

2. WCK116-1119, filed April 19, 2017, are references cited in the Reply Declaration of Ian McKeague, Ph.D. These exhibits were submitted with Petitioner's Reply in IPR2016-01582 on April 19, 2017.

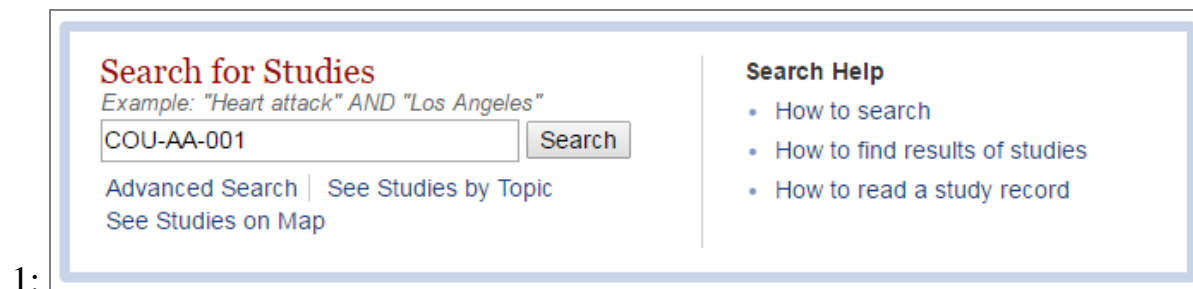
3. WCK116, filed on April 19, 2017, is a true and correct copy of the American Cancer Society website page, "Hormone therapy for prostate cancer," accessible at <https://www.cancer.org/content/cancer/en/cancer/prostate-cancer/treating/hormone-therapy.html>, last visited April 10, 2017. An exhibit label was added to this exhibit and no other alterations were made.

4. WCK118, filed on April 19, 2017, is a true and correct copy of the NIH National Cancer Institute website page, "Metastatic cancer," accessible at <https://www.cancer.gov/types/metastatic-cancer.html>, last visited April 14, 2017. An exhibit label was added to this exhibit and no other alterations were made.

5. WCK117, filed on April 19, 2017, is a true and correct copy of the NIH National Cancer Institute website page, "Prostate-specific antigen (PSA) test," accessible at <https://www.cancer.gov/types/prostate/psa-fact-sheet>, last visited

April 11, 2017. An exhibit label was added to this exhibit and no other alterations were made.

6. WCK1119, filed on April 19, 2017, is a true and correct copy of the Cougar Biotechnology, Inc., Clinical Study Report: COU-AA-001 and COU-AA-001 EXT dated November 17, 2010, accessible through <https://clinicaltrials.gov>. An exhibit label was added to this exhibit and no other alterations were made. WCK119 was obtained by (1) searching [clinicaltrials.gov](https://clinicaltrials.gov) for the “COU-AA-001” study, (2) clicking on the first result, (3) scrolling down to the bottom of the page and clicking on the link provided under the “More Information” heading, (4) clicking on the URL provided, and (5) clicking on the downloaded PDF. See the following screenshots for a depiction of how WCK1119 was obtained:



2:

Rank	Status	Study
1	Completed	<a href="#">An Expanded Access Study of Abiraterone Acetate in Patients With Advanced Prostate Cancer Who Have Completed Clinical Study COU-AA-001</a> Condition: Prostate Neoplasms Interventions: Drug: Abiraterone acetate; Drug: Glucocorticoid
2	Completed Has Results	<a href="#">A Safety and Efficacy Study of Abiraterone Acetate in Participants With Prostate Cancer Who Have Failed Hormone Therapy</a> Condition: Prostatic Neoplasms Interventions: Drug: Abiraterone acetate; Drug: Abiraterone acetate MTD; Drug: Dexamethasone

3:

▶ More Information

Additional Information:

[An Expanded Access Open Label Study of CB7630 \(Abiraterone Acetate\) in Patients with Advanced Prostate Cancer Who Have Completed CB7630 Clinical Study COU-AA-001](#)

4:

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You are about to leave ClinicalTrials.gov and go to:

URL: [http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR\\_JNJ\\_6051&studyid=2388&filename=CR016912\\_CSR.pdf](http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR_JNJ_6051&studyid=2388&filename=CR016912_CSR.pdf)

Label: An Expanded Access Open Label Study of CB7630 (Abiraterone Acetate) in Patients with Advanced Prostate Cancer Who Have Completed CB7630 Clinical Study COU-AA-001

Click on the link to continue.

Or return to: [ClinicalTrials.gov Home](#)

5:



CR016912\_CSR (4).pdf



7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed this 10<sup>th</sup> day of May 2017.

Respectfully submitted,

**Lestin L. Kenton Jr. (Reg No. 72,314)**