

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., ACTAVIS  
LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC,  
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S  
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, INC.,  
TEVA PHARMACEUTICALS USA, INC., WEST-WARD  
PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

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Case IPR2016-01332<sup>1</sup>

Patent 8,822,438 B2

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**DECLARATION OF BRYAN D. BEEL**

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<sup>1</sup>Case IPR2017-00853 has been joined with this proceeding.

1. I, Bryan D. Beel, am over the age of eighteen 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 am an attorney at Perkins Coie LLP, counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan” or “Petitioner”) in connection with the above-captioned *inter partes* review (“IPR”).

3. Exhibits MYL 1088 and 1141, filed April 19, 2017, are references cited in the Reply Declaration of Ivan T. Hofmann.

4. Exhibit MYL 1088, filed on April 19, 2017, is a true and correct copy of a BTG press release entitled, “BTG Licenses New Prostate Cancer Drug to Cougar Biotechnology,” dated April 20, 2004, accessible at <https://www.btgplc.com/media/press-releases/btg-licenses-new-prostate-cancer-drug-to-cougar-biotechnology/> (last visited April 3, 2017). An exhibit label was added to this exhibit upon its retrieval from the listed website, and a deposition exhibit label was added on April 5, 2017, during the deposition of Dr. Christopher Vellturo; no other alterations were made.

5. Exhibit 1089 is a reference used during the deposition of Christopher Vellturo, Ph.D., on April 5, 2017.

6. Exhibit MYL 1089, filed on April 19, 2017, is a true and correct copy of the Zytiga website page, “About Zytiga® (abiraterone acetate),” accessible at

<https://www.zytiga.com/choosing-zytiga/about-zytiga> (last visited April 3, 2017). When scrolling down the page, the website URL changes from the above-listed URL to <https://www.zytiga.com/choosing-zytiga/how-zytiga-works> (middle of page) and then <https://www.zytiga.com/choosing-zytiga/results-of-zytiga> (end of page). An exhibit label was added to this exhibit, a deposition exhibit label was added on April 5, 2017, during the deposition of Dr. Christopher Vellturo, and no other alterations were made.

7. Exhibits 1092–95, filed April 19, 2017, are references cited in the Reply Declaration of Ian McKeague, Ph.D.

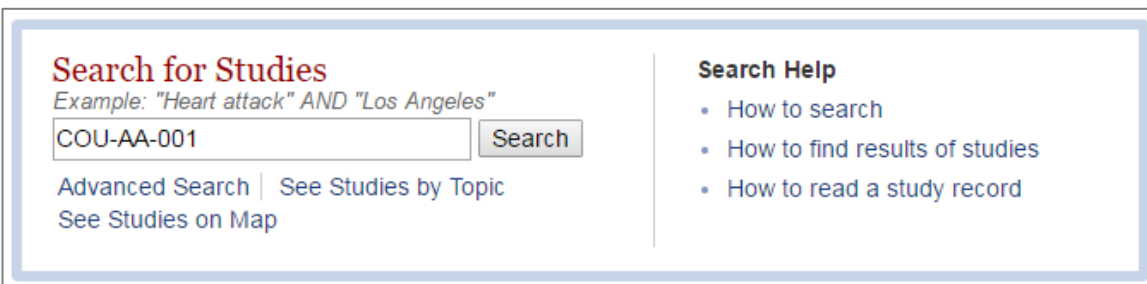
8. Exhibit MYL 1092, filed on April 19, 2017, is a true and correct copy of the American Cancer Society website page, “Hormone Therapy for Prostate Cancer,” accessible at <https://www.cancer.org/content/cancer/en/cancer/prostate-cancer/treating/hormone-therapy> (last visited April 10, 2017). An exhibit label was added to this exhibit and no other alterations were made.

9. Exhibit MYL 1093, 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> (last visited April 14, 2017). An exhibit label was added to this exhibit and no other alterations were made.

10. Exhibit MYL 1094, 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.

11. Exhibit MYL 1095, 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>. The document 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 Exhibit MYL 1095 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> <b>Condition:</b> Prostate Neoplasms <b>Interventions:</b> 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> <b>Condition:</b> Prostatic Neoplasms <b>Interventions:</b> 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:

Home > Exit Notice Text Size ▼

Exit Notice

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 ^

An exhibit label was added to this exhibit and no other alterations were made.

12. Exhibits 1117 and 1125, filed April 19, 2017, are references cited in the Reply Declaration of Marc B. Garnick, M.D.

13. Exhibit MYL 1117, filed on April 19, 2017, is a true and correct copy

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