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Date of Electronic (EFS) Transmission: July 3, 2012

Signature: /Laurie A. Phillips/ Name: Laurie A. Phillips

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

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|---|---|---|---|
| Applicant(s): | Alan H. Auerbach | Conf. No.: | 1597 |
| Application No.: | 13/034,340 | Group Art: | 1628 |
| Filing Date: | February 24, 2011 | Examiner: | San Ming R. Hui |
| Title: | Methods and Compositions for Treating Cancer | | |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE**

Dear Sir:

In response to the Office Action mailed February 3, 2012, Applicants submit the following amendments and remarks.

**Remarks/Arguments** begin on page 2 of this paper.

Remarks

**Rejections Under 35 U.S.C. § 103**

Claims 37-56 are rejected under 35 USC §103(a) as allegedly being unpatentable over O'Donell et al. (British Journal of Cancer (2004)), in view of Tannock et al. (Journal of Clinical Oncology (1996)). Applicant respectfully traverses this rejection.

The invention is directed to a method for treating prostate cancer by administering both abiraterone acetate and prednisone to a patient. The Office alleges this invention is obvious by a combination of O'Donnell, which discloses administration of certain doses of abiraterone acetate to castrated prostate cancer patients, and Tannock, which discloses administration of prednisone in combination with a chemotherapy agent to prostate cancer patients.

Applicant believes that the Office has failed to establish a case of obviousness. At the very most, the cited art may suggest that a combination of abiraterone acetate and prednisone would be obvious to try; along with a myriad of other combinations of two cancer drugs. Nothing in the art teaches or suggests that abiraterone acetate in combination with prednisone would be a particularly useful combination for cancer treatment.

Even if one of ordinary skill would have been motivated to combine both modes of treatment, the claimed invention produces unexpected results. Applicants enclose herewith Sartor, *Nature Reviews Clinical Oncology*, 8:515-516 (2011) ("Sartor"). Sartor reports on the results of a clinical study on patients with prostate cancer who were treated with the claimed invention. According to Sartor, "Abiraterone plus prednisone prolongs overall survival relative to prednisone alone. . ." Sartor, abstract. Additionally, "reported pain was markedly reduced in the abiraterone plus prednisone arm. Second, preliminary reports indicate that circulating tumors cells (CTCs)—a novel biomarker indicative of poor prognosis —were reduced in the experimental arm and that a combination of levels

of lactate dehydrogenase (LDH) and CTCs at baseline and changes in these levels after treatment may predict survival, independently of therapy, in patients with an elevated baseline CTC count." Thus, the claimed invention produces the unexpected results of increased survival, reduced pain, and lower levels of a biomarker connected with survival.

The claimed invention has experienced an impressive commercial success. Applicant attaches herewith the label for abiraterone acetate, sold under the tradename ZYTIGA. According to the label, "ZYTIGA in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel." Thus, the ZYTIGA label directs patients to practice the claimed invention.

ZYTIGA was approved for sale in the U.S. in April 2011. Within the first year of release, worldwide sales were over $400 million. Sales for the truncated 2011 year totaled $200 million worldwide. Sales for just the first quarter of 2012 were also $200 million. Thus, not only did the claimed invention enjoy immediate commercial success, this commercial success grew over the first year of commercial availability.

The claimed invention displays unexpected results over the prior at, and shows commercial success. Thus, the present claims are non-obvious over the cited art. Accordingly, Applicant requests reconsideration and withdrawal of the rejection under 35 USC §103(a).

**Double Patenting Rejection**

Claims 37-56 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 9, 19, 21, 24, 29-32 of copending U.S. Patent Application No. 12/898,149 (the '149 application). The '149 application has been a abandoned. Thus, this rejection is now moot.

## III. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the office require anything further, it is invited to contact applicants' representative at the telephone number below.

Respectfully submitted,

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