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

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

## In re Application of:

| 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 final Office Action mailed March 4, 2013, Applicant submits the following amendments and remarks.

A list of the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.



**Listing of Claims:** 

1-36. (Canceled).

37. (Previously presented) A method for the treatment of a prostate cancer in a human

comprising administering to said human a therapeutically effective amount of abiraterone

acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective

amount of prednisone.

38. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is from

about 50 mg/day to about 2000 mg/day.

39. (Previously presented) The method of claim 38, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is from

about 500 mg/day to about 1500 mg/day.

40. (Previously presented) The method of claim 39, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is about

1000 mg/day.

41. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the abiraterone acetate or a pharmaceutically acceptable salt thereof is

administered in at least one dosage form comprising about 250 mg of abiraterone acetate

or a pharmaceutically acceptable salt thereof.

42. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the prednisone is from about 0.01 mg/day to about 500 mg/day.

43. (Previously presented) The method of claim 42, wherein the therapeutically effective

amount of the prednisone is from about 10 mg/day to about 250 mg/day.

44. (Previously presented) The method of claim 44, wherein the therapeutically effective

amount of the prednisone is about 10 mg/day.

45. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the prednisone is administered in at least one dosage form comprising about 5

mg of prednisone.

46. (Previously presented) The method of claim 37, comprising administering to said

human about 500 mg/day to about 1500 mg/day of abiraterone acetate or a

pharmaceutically acceptable salt thereof and about 0.01 mg/day to about 500 mg/day of

prednisone.

47. (Previously presented) The method of claim 46, comprising administering to said

human about 1000 mg/day of abiraterone acetate or a pharmaceutically acceptable salt

thereof and about 10 mg/day of prednisone.

48. (Previously presented) The method of claim 37, wherein said prostate cancer is

refractory prostate cancer.

49. (Previously presented) The method of claim 48, wherein the refractory prostate

cancer is not responding to at least one anti-cancer agent.

50. (Previously presented) The method of claim 49, wherein the at least one anti-cancer

agent comprises a hormonal ablation agent, an anti-androgen agent, or an anti-neoplastic

agent.

51. (Previously presented) The method of claim 50, wherein the hormonal ablation agent

comprises deslorelin, leuprolide, goserelin, or triptorelin.

52. (Previously presented) The method of claim 50, wherein the anti-androgen agent

comprises bicalutamide, flutamide, or nilutamide.

53. (Previously presented) The method of claim 50, wherein the anti-neoplastic agent

comprises docetaxel.



54. (Previously presented) The method of claim 48, comprising administering to said

human about 500 mg/day to about 1500 mg/day of abiraterone acetate or a

pharmaceutically acceptable salt thereof and about 0.01 mg/day to about 500 mg/day of

prednisone.

55. (Previously presented) The method of claim 54, comprising administering to said

human about 1000 mg/day of abiraterone acetate or a pharmaceutically acceptable salt

thereof and about 10 mg/day of prednisone.

56. (Previously presented) The method of claim 53, comprising administering to said

human about 1000 mg/day of abiraterone acetate or a pharmaceutically acceptable salt

thereof and about 10 mg/day of prednisone.

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